(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 March 2001 (01.03.2001)

PCT

(10) International Publication Number
WO 01/14012 A1

(51) International Patent Classification[7]: A61N 5/06

(21) International Application Number: PCT/US00/22720

(22) International Filing Date: 18 August 2000 (18.08.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/379,703 24 August 1999 (24.08.1999) US

(71) Applicant and
(72) Inventor: RUSSELL, Thomas, A. [US/US]; 7 Mustang Road, Rancho Palos Verdes, CA 90275 (US).

(74) Agents: UXA, Frank, J. et al.; Stout, Uxa, Buyan & Mullins, LLP, 4 Venture #300, Irvine, CA 92618 (US).

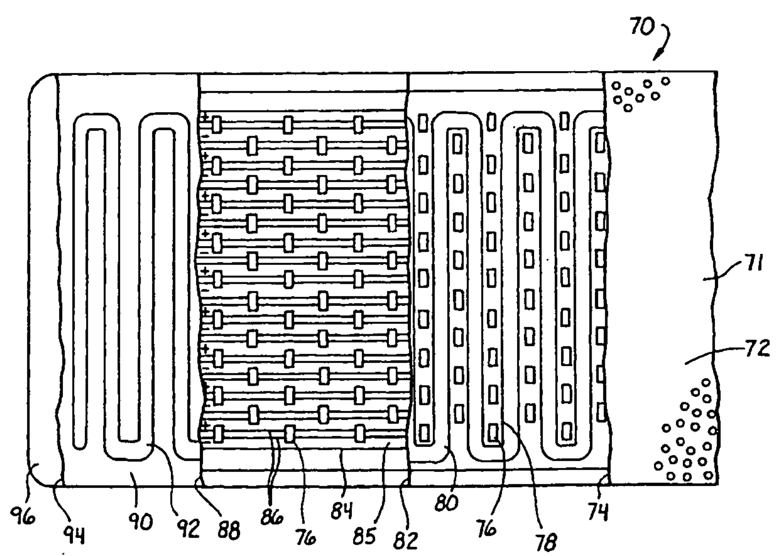
(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*
— *With amended claims.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: FLEXIBLE ILLUMINATORS FOR PHOTOTHERAPY



(57) Abstract: A flexible illuminator (30) for external phototherapy is disclosed having at least one light generating source (76), preferably a plurality of light generating sources, on a flexible substrate (84). The flexible substrate may be a printed circuit board, and the light generating sources may be surface mount LEDs. Structure for diffusing light (111) from the discrete light sources, and/or a system for transferring heat away from a skin contact surface are provided. The illuminator may be formed as a pad (64) to be wrapped around an infant or a limb of an adult, or as a mat (60). The illuminator may be passively or actively cooled so that the skin contact surface remains below the desired temperature. The LED is preferably blue or green, and an ultraviolet filter (110) may

WO 01/14012 A1

FLEXIBLE ILLUMINATORS FOR PHOTOTHERAPY

Field of the Invention

The present invention pertains to devices and methods of external phototherapy and, in particular, to phototherapy devices for use in close proximity or in contact with the skin of the patient. More specifically, the present invention provides a flexible, high-intensity flexible phototherapy device that can be safely and comfortably worn.

Background of the Invention

The term "phototherapy" relates to the therapeutic use of light, and as used herein, the term "illuminator" refers to a device that is intended to be used externally to administer light to the skin for therapeutic purposes. Some phototherapy devices, in contrast, are provided on probes and are designed to be used internally.

External phototherapy has been shown effective in treating various medical conditions. For example, studies have shown that certain light spectra are effective in treating bulimia nervosa, herpes, psoriasis, seasonal affective disorder, sleep disorders, acne, and other conditions. One of the conditions most widely treated with phototherapy is hyperbilirubinemia in newborn infants, typified by an elevated level of a toxic molecule known as bilirubin in the infant's blood. During a natural process where the body scavenges iron from a substance known as "heme," bilirubin is produced. Normally, bilirubin is a conjugated within the liver and excreted. A fetus cannot conjugate bilirubin, however, so it is cleared via the placenta. During the initial neonatal period, the infant's liver may be too immature to conjugate bilirubin. If the condition remains untreated, the serum bilirubin levels may

increase to the clinical condition of jaundice, since there is no effective excretory pathway. High levels of bilirubin in the neonate may cause irreversible brain damage and even death.

About 60 percent of newborns become clinically jaundiced at some time during the first week of life. Consequently, hyperbilirubinemia is one of leading causes of hospital readmissions of newborns. Phototherapy is the treatment of choice for neonatal unconjugated hyperbilirubinemia, and has been used worldwide for decades with no known significant side effects. Phototherapy treats hyperbilirubinemia by changing bilirubin from its non-water-soluble form to water-soluble byproducts which can be bound to albumin, transported to the liver, and excreted.

As a yellowish pigment, bilirubin absorbs visible light in the blue, violet, and green spectra, and most readily absorbs wavelengths in the range of 400-500 nm, with a maximum absorption peak in the 450-460 nm range, i.e., blue light. Green light is also effective in phototherapy because light of longer wavelengths penetrates the skin more deeply. There is a dose-response relationship in the efficacy of phototherapy. That is, there is an increased response for higher doses of therapeutic light, as shown by a decrease in bilirubin levels.

Illuminators for phototherapy which are known in the art fall into two general categories: banks of light and fiber-optic illuminators. The earliest phototherapy illuminators included banks of light placed over an incubator, above an open bassinet, under a hood, or under a transparent support. Either fluorescent tubes or metal halide lamps typically serve as the light sources, although arrays of LEDs are also known in the art. These light sources are spaced from the infant and illuminate the whole

body of the infant.

Illuminators using banks of light suffer from a number of drawbacks. The infant must wear sometimes uncomfortable eye protection during this treatment, either by using an appropriate shield or goggles, or even by taping the eyes shut, because the intense light can cause permanent eye damage. The relatively large size of the equipment takes up valuable free space in a typically cramped neonatal hospital ward. The banks of lights generate undesirable heat, and interfere with personnel attending to the patient. The heat generated is of vital concern in infant phototherapy. Newborn infants are extremely sensitive to heat, and it has been found that the heart rate of preterm infants increases significantly when the environmental temperature is raised as little as five degrees Celsius above normothermia. Hyperthermia has been associated with heart irregularities, heatstroke, and sudden infant death syndrome. Consequently, the infant's temperature must be frequently monitored when the infant is under a bank of phototherapy lights. Moreover, the relatively bulky equipment is not well-suited for home use, and thus the newborn infant must remain longer in the hospital.

Primarily in response to the desire of parents to bring their newborn infant home sooner, portable fiber-optic pads or wraps have been developed. These fiber-optic illuminators transmit light from a remote source through a fiber-optic cable to a flexible pad having a weave of optical fibers which can be worn next to the patient's skin. Because fiber-optic illuminators are placed around or under only a portion of the infant, its eyes are not exposed to intense light and eye protection is not necessary. Because the light source is remote from the flexible pad next to the patient, a filter can be used to attenuate any appreciable heating. Most importantly, since infant can be held and attended to while undergoing

phototherapy treatment, fiber-optic illuminators promote better infant-parent bonding during the first few weeks of life. Commercial fiber-optic phototherapy illuminators include Ohmeda's BiliBlanket and Respironics' Wallaby II, which have tungsten halogen lamps and quartz halogen lamps, respectively, as their light sources.

Figure 1 illustrates a fiber-optic pad type of illuminator of the prior art. The illuminator includes a woven fiber-optic pad 10 connected by a cable 12 to a housing 14 for a source of light. The connector 16 is affixed to an end of the cable 12 and is inserted into the housing 14 to receive the light energy. The housing 14 includes the front face 24 on which may be mounted a power switch 20, a control indicator 22, and indicator lights 26 and 28. The pad 10 comprises a plurality of optical fibers woven so as to emit light energy from one side of the pad.

Despite several advantages over radiant-type illuminators, fiber-optic illuminators are not ideal for several reasons. Significantly, fiber-optic illuminators typically deliver a lower overall amount of light than overhead banks of light, because the light is transmitted from a remote source to a relatively small fiber-optic pad. Moreover, to deliver even this limited amount of light, fiber-optic illuminators require a high-intensity light source such as halogen lamp, and an expensive optical filter to eliminate unwanted heat and ultraviolet light. Fiber-optic pads typically rely upon the geometry of the various emitting layers of fiber to control the level of light emittance. Since the patient is in direct contact with the fiber-optic pad, there is some pressure applied which may change the geometry, and thus change the level of light. Finally, the light intensity may be more concentrated near the light source than at the other end of the pad.

Recently, researchers at Stanford University have

studied the efficacy of high-intensity light-emitting diodes (LEDs) for phototherapy of hyperbilirubinemic neonates. The in vitro photodegradation of bilirubin in human serum albumin from both LEDs and conventional light sources was measured, with the conclusion that LEDs are more effective. The use of LEDs for use in home phototherapy devices was mentioned. However, no specific device structure was disclosed, nor was any consideration given for the safety and comfort of the patient, for example newborn infants, undergoing phototherapy..

In sum, fiber-optic illuminators are less effective than traditional overhead phototherapy illuminators, and both have significant disadvantages. In addition, there remains a number of hurdles, for example, relating to patient safety and comfort as well as therapeutic effectiveness, to the use of LEDs in home phototherapy devices. There thus remains a need for a phototherapy illuminator which delivers a higher intensity of therapeutic light than current fiber-optic illuminators, while retaining the advantages of a flexible light-emitting pad and being safe and comfortable in use.

Summary of the Invention

In accordance with one aspect of the present invention, an illuminator for delivering light energy to the skin for phototherapy is disclosed. The illuminator comprises a thin, lightweight flexible substrate having a plurality of conductive traces affixed thereto adapted to connect to electrical power source. At least one discrete light generating source, preferably at least two discrete light-generating sources, are disposed on the substrate and are coupled to the conductive traces. Finally, a covering at least partly surrounds the substrate and has an exterior surface that is spaced apart from the light-generating

sources, the exterior surface being adapted to contact the skin of patient. Desirably, the illuminator is sufficiently lightweight and flexible to be worn against the skin of a newborn infant without injury. The illuminator preferably includes a light diffuser to render the light energy from the discrete light-generating sources more uniform. Additionally, the cooling means is desirably provided to maintain the exterior surface below a predetermined temperature.

In another embodiment, the present invention provides an illuminator for delivering light energy to the skin for phototherapy, comprising a thin, lightweight substrate, a plurality of conductive traces affixed to the substrate and adapted to connect to an electrical power source, at least one light-generating source disposed on the substrate and coupled to the conductive traces, and an interface at least partly covering or adjacent the light-generating source on the substrate.

As used herein, the term "interface" refers to a region of the present illuminator located at least partially around and/or at least partially adjacent the light generating source or sources of the illuminator. The interface can include a hollow or open space or passage.

The interface advantageously provides or is adapted to carry an effective heat transfer means or medium to dissipate heat generated by the light-generating source or sources so that the illuminator can safely contact the skin of the patient, for example, a neonate. In one useful embodiment, the illuminator includes a covering and the interface provides or is adapted to carry a cooling means or medium between the covering and the substrate. For example, the interface may define spaces between the covering and a substrate for passive or active heat transfer. The illuminator may be provided in a flexible mat connected to one or more conduits carrying electrical

wires and the cooling fluid medium.

In a still further embodiment, an illuminator of the present invention for delivering light energy to the skin for phototherapy comprises a thin, lightweight substrate and a plurality of conductive traces affixed to the substrate adapted to connect to electrical power source. At least one discrete light source, preferably at least two discrete light sources, disposed on the substrate are coupled to the conductive traces. An interface at least partly covers the light-generating sources on the substrate, and is effective to diffuse the light emitted from the discrete light source or sources. The illuminator is adapted to contact the skin of the patient. The interface may include any suitable light diffuser or diffusers. For example, light scattering elements, such as glass bubbles or hollow glass beads, and the like may be employed. Other light scattering elements include, but are not limited to, grains or particles of titanium oxide, titanium dioxide, zirconium oxide, zinc oxide, quartz, aluminum oxide, diamond dust, calcium carbonate, calcium fluoride, flint glass, barium fluoride, other glasses, material which has a refractive index different, e.g., by at least about 5%, from the refractive index of the matrix in which the light scattering elements are placed, and the like and mixtures thereof. The interface may include indentations, texturing and the like surface features to diffuse the light. A reflector or reflectors may be employed to diffuse light. Also, a lambertian (random) reflecting surface or surfaces, for example, a white surface or surfaces, may be employed to diffuse light. Of course, combinations of two or more light diffusers can be employed.

The interface may comprise a silicone matrix with glass beads or bubbles, for example, hollow glass beads, dispersed therethrough, or a blend, mixture or combination

of materials having different refractive indexes. Alternately, or in addition, the interface may have an exterior surface adapted to contact the skin of a patient, which surface is irregular, for example, having a matte finish, to defuse the light emitted from the discrete light source or sources.

In one preferred embodiment of the invention, light scattering elements, such as glass bubbles and the like, are positioned in proximity to the surface of the illuminator to be in contact with the patient, that is the contact surface. The light sources or sources are located further back or away from the contact surface and a flexible lambertian reflecting surface is located still further away from the contact surface. This arrangement reduces the loss of light and enhances light diffusion and utilization. The illuminator is placed against the skin of the patient, leaving substantially no room for the light to escape. The reflecting surface is effective to return light scattered by the patient's tissue and/or the diffusing elements back to the patient until it is absorbed, and does so at a close distance, maintaining light intensity. Concentrated light from the light source is spread over the surface of the reflector, further enhancing diffusion. This arrangement also allows the use of additional diffusing material while maintaining a substantially constant level of light output.

Preferably, the average irradiance at the light emitting or contact surface of the present illuminators is more than about 50 micro watts per square centimeter.

In a further aspect of present invention, a wearable phototherapeutic illuminator for delivering light energy to the skin comprises a flexible substrate and a least one light-generating source disposed on the substrate. A flexible, polymer layer covers the light-generating source, the layer permitting light energy to penetrate therethrough

and being adapted to substantially conform, or structured to be capable of substantially conforming, to a portion of the skin of the patient. The layer is desirably a material chosen from the group consisting of silicone, urethane, and polyurethane. There may be a plurality of the light-generating sources, and a plurality of glass bubbles, or a blend of materials having different refractive indexes, may be dispersed throughout the layer to defuse the light emitted from the light-generating sources.

Each of the features disclosed herein is included within the scope of the present invention. In addition, all combinations of two or more of the presently disclosed features which are not mutually inconsistent or incompatible are also included within the scope of the present invention.

These and other aspects and advantages of the present invention are apparent in the following detailed description and claims, particularly when considered in conjunction with the accompanying drawings in which like parts bear like reference numerals.

Brief Description of the Drawings

Figure 1 is a perspective view of a prior art fiber-optic illuminator;

Figure 2 is a perspective view of a flexible pad-type illuminator of the present invention;

Figure 3 is a schematic view of a phototherapy system utilizing a flexible pad-type illuminator of the present invention;

Figure 3A is a schematic illustration of the control housing of the phototherapy system shown in Figure 3;

Figure 4 is a perspective view of alternative mat-type illuminator of the present invention;

Figure 5 is a perspective view of a flexible pad-type

illuminator of the present invention wrapped around an adult limb;

Figure 5A is an illustration of an illuminator of the present invention in the form of a mask to be worn on the face of an adult or adolescent human.

Figure 6 is a plan view of a pad-type illuminator of the present invention showing sequential layers cutaway;

Figure 7 is a sectional view through a portion of the illuminator of Figure 6;

Figure 8 is a sectional view through a portion of an alternative illuminator similar to that shown in Figure 6;

Figure 9 is a plan view of a substrate and electronic connections for a plurality of light-generating sources used in an exemplary illuminator of the present invention;

Figure 10 is a partial cutaway view of internal cooling channels formed in an exemplary illuminator of the present invention;

Figures 11A-11D are cross-sectional views showing various constructions of the illuminator of the present invention;

Figures 12A-12F are cross-sectional views showing further constructions of the illuminator of the present invention;

Figures 13A-13D are cross-sectional views showing still further constructions of the illuminator of the present invention;

Figures 14A-14C are plan views of illuminators of the present invention having passive cooling channels therein;

Figures 15A-15C are perspective views of illuminators of the present invention having external cooling fins formed thereon; and

Figure 16 is a perspective view of an alternative illuminator having internal spacer pins.

Figure 17 is a perspective illustration showing a still further construction of an illuminator in accordance

with the present invention.

Figures 17A-D are schematic illustrations of various patterns useful in the construction illustrated in Figure 17.

Description of the Preferred Embodiments

The present invention provides a flexible illuminator having a variety of applications, such as for the treatment of hyperbilirubinemia in neonates, and psoriasis, seasonal affective disorder, sleep disorders, herpes, acne, and other medical conditions. The invention is an advance over current fiber-optic type illuminators because of the increased intensity of the light sources. Various configurations are described herein, none of which should be construed as particularly preferred in general. Instead, each configuration may be preferred in certain applications over others.

Illuminator System

Figure 2 illustrates an illuminator 30 of the present invention comprising an elongate flexible body 32 having a front or contact surface 34 and a back surface facing the opposite direction and not seen in Figure 2. In the embodiment illustrated, the illuminator 30 has a rounded rectangular configuration with a length L, a width W, and a thickness t, with the length L being substantially greater than the width W, both of which are substantially greater than the thickness t. The proportion of these dimensions is preferred to enable the illuminator 30 to be wrapped around a small infant, or around the limb of an adult, as seen in Figures 3 and 5, although those of skill in the art will understand that other configurations are possible.

As will be described in more detail below, the illuminator 30 contains a plurality of electric light-

generating sources, and thus a power cable 36 attaches to a first narrow end 38 of the body 32. The body 32 is thicker in a region 40 adjacent the first end 38 to provide strain relief at the interface between the body and cable 36. In one particular preferred embodiment, the body 32 is molded around the light-generating sources and power cable 36, with the thickened region 40 being formed accordingly. As will also be described below, the illuminator 30 may include means for transferring heat away from the front surface 34, which may involve flow of a cooling medium to interior channels formed in the body 32. In that case, the jacket around the power cable 36 may also provide a conduit for delivery of the cooling medium to and from the illuminator 30.

Illuminator Configurations

Figures 3, 3A, 4, 5 and 5A illustrate several potential configurations of the illuminator of the present invention. In Figure 3, an illuminator 44 similar to that shown in Figure 2 is wrapped completely around the abdomen of an infant patient. The illuminator 44 may be secured in this position using straps, Velcro, adhesive tape adhered to a disposable cover, or other such attachment means. A cable 46 supplies electricity and cooling medium from a control housing 48 to the illuminator 44, as mentioned above. Figure 3 schematically illustrates a control assembly 49 (of conventional design) providing electricity to illuminator 44 through power conduit 51. Control assembly 49 also controls the operation of an active cooling system 50 including a source of cooling medium 52 and a pump 54. Source 52 may include cooling coils or other suitable assembly for maintaining the temperature of the cooling medium or coolant at a desired level. A pair of conduits 56 and 57 deliver the cooling medium to the illuminator 44 and return medium to be cooled to the system

50.

Figure 4 illustrates a larger, mat-type illuminator 60 upon which an infant may be placed. A single cable 62 supplies power (and possibly cooling medium) to the illuminator 60.

Figure 5 illustrates a pad-type illuminator 64, much like the illuminator 30 illustrated in Figure 2, that is wrapped around the patient's limb and fastened with Velcro hook/loop fastener patches 66. Again, a single conduit 68 delivers power and potentially cooling medium to the illuminator 64.

Figure 5A illustrates a further specialized form of an illuminator in accordance with the present invention. This illuminator 61 is in the form of a mask to be placed on the face of an adult or adolescent human. An elastic band 63 is attached to mask 61 and is placed around the patient's head to secure the mask in a desired position on the face. Eye holes 65, nose hole 67 and mouth hole 69 are provided so that the eyes can be protected from the light and normal breathing/talking can occur while the patient is being treated, for example, for acne. A single conduit 59 delivers electrical power and possibly cooling medium to the mask 61.

Illuminators in accordance with the present invention can be formed into any suitable configuration to treat various medical conditions, as described herein, while also protecting the patient from unwanted, and possibly harmful exposure to light and/or heat. For example, the present illuminators can be configured to be placed on the face, like a wash cloth, for the treatment of seasonal affective disorder, as well as acne and other skin conditions; or can be configured similarly to a sanitary napkin, tampon or condom for the treatment of herpes.

In short, the forms of the present illuminators illustrated are not intended, and should not be taken, to

be limiting.

Exemplary Illuminator Construction

Figures 6-7 illustrate the internal construction of an illuminator similar to that shown in Figure 2. The plan view of Figure 6 shows one end of the body 70 of the illuminator with sequential layers stripped away from right to left. These layers can be seen in cross-section in Figure 7. The front or contact surface 71 of the body 70 faces out of the page in Figure 6. Therefore, a front covering 72 is seen on the right side of Figure 6, and is cut away at line 74 to reveal an array of light-generating sources 76. A plurality of glass bubbles 73 (right side of Figure 7) are randomly located in front covering 72 to scatter or diffuse light, as discussed hereinafter. In this embodiment, a plurality of transversely extending spacers 78 surround the sides of each of the light-generating sources 76, and are spaced from one another to provide cooling channels 80 therebetween. The spacers 78 may or may not at least partially encapsulate the sources 76. Such encapsulation is preferred to enhance dissipation of heat and light diffusion, and to protect the light sources from physical damage and/or detachment. As is apparent from Figure 6, the cooling channels 80 extend in a serpentine fashion along the length of the body 70. The layer of spacers 78 is cut away at line 82 in Figure 6 to reveal a substrate 84 on which the light-generating sources 76 are mounted. In addition, an array of conductive traces 86 is provided on the substrate 84 to power the light-generating sources 76. Continuing to the left in Figure 6, the substrate layer is cut away at line 88 to reveal a layer of secondary spacer material 90 within which is formed a secondary cooling channel 92. Again, the cooling channel 92 extends in a serpentine fashion along the length of the body 70 and adjacent the substrate. Finally, the

secondary spacer material 90 is cut away at line 94 to reveal a back cover 96.

Alternative Illuminator Construction

Figure 8 illustrates, in cross-section, an illuminator 100 having a substrate 102 with a plurality of light-generating sources 104 mounted thereon. An array of spacers 106 between cooling channels 108, as in Figure 7, is provided. In addition, an insulating layer 110 and outer covering 112 are included in the combination of components making up the interface. Also included are a plurality of glass bubbles 111 located in a relatively well defined layer in outer covering 112 to scatter or diffuse light, as discussed hereinafter. As with Figure 7, the backing comprises the secondary spacer 114 and secondary cooling channels 116 encompassed by the back cover 118. The addition of an insulating layer 110 further helps to prevent heat transfer from the light generating sources 104 to the contact surface of the illuminator.

Internal Illuminator Systems

Figure 9 is a cutaway view of one end of an illuminator 120 of the present invention showing the interface between a power cable 122 and an array of conductive tracings 124 providing a conductive path to a plurality of light-generating sources 126. A wire 128 electrically connects to a pole 130 that is in electrical communication with the negative terminal of each of the light-generating sources 126. Likewise, a wire 132 electrically connects to a pole 134 that is in electrical communication with the positive terminal of each of the light-generating sources 126. The wires may be electrically connected to the tracings by lap soldering to the pole or bus bar or through use of DIMM or MOLEX-type multiconductor connectors. In this embodiment, the light-

generating sources are provided in seventeen rows across the width of the illuminator 120, and are staggered from column to column. That is, a first column 136 of nine light-generating sources is followed by a second column 138 of eight light-generating sources in different rows of conductive tracings 124. This pattern repeats itself along the length of the illuminator 120.

Figure 10 illustrates the relative positions of the light-generating sources 126, a first cooling channel 140, and secondary cooling channel 142 provided below the substrate. Arrow 144 indicates an inflow of cooling medium to the first cooling channel 140, which medium flows between columns of light-generating sources 126. The horizontal cutaway line 146 reveals the secondary cooling channel 142 below the substrate. Although not shown, the first cooling channel 140 is in fluid communication with the secondary cooling channel 142 at the opposite end of the illuminator. That is, the cooling medium flows along the length of the illuminator 120 (from right to left), and then passes across the plane of the substrate (i.e., into the page) through an opening into the secondary cooling channel 142. The cooling medium then flows (from left to right) along the length of the secondary cooling channel 142 until it exits the illuminator, as indicated by arrow 148.

Figure 10 thus illustrates active cooling of the illuminator 120, wherein cooling medium is propelled through internal channels. The cooling medium in this regard may be in liquid or gaseous form, with air being preferred to avoid increasing the weight of the illuminator 120 in use. Of course, other arrangements of cooling means are possible, as will be described in more detail below.

Functional Considerations

Now with reference more particularly to the cross-

section of Figure 7, the illuminator can be viewed more generally as including the light-generating sources 76 mounted on the substrate 84, and an interface provided between the substrate 84 and a front or contact surface 98. In the illustrated embodiment, contact surface 98 comprises the outer surface of the covering 72, while the interface comprises a combination of the covering, the spacers 78, and the cooling channels 80. In addition, the illuminator preferably includes a backing, which in this embodiment comprises the secondary spacers 90, secondary cooling channels 92, and back cover 96. The invention may be best described in terms of the preferred functional characteristics of the interface and the backing, as follows.

The interface preferably performs two main functions: heat insulation and light diffusion. That is, the separate light-generating sources 76 generate some heat in operation which must be intercepted and carried away or attenuated before it reaches the contact surface 98. Therefore, the interface preferably provides a thermal barrier to heat conduction, and may also include a system of passive or active cooling, facilitated by the cooling channels 80. In addition, the light-generating sources 76, being discrete and spaced apart, create a plurality of points of intense light, rather than an even distribution. Therefore, the interface preferably diffuses the discrete points of light to provide a more uniform emittance. In addition, the interface performs other functions. For example, the interface protects the light sources and circuitry from damage and/or detachment, reduces or even eliminates the risk of exposing the patient to electrical current, and provides additional padding to enhance the comfort of the patient.

The backing preferably performs two main functions as well: heat conduction and light reflection. That is, the

backing preferably provides an effective heat sink for the heat generated by the light-generating sources 76, which works in conjunction with the heat barrier provided by the interface to cause heat to travel away from the contact surface 98. In this manner, the secondary spacer 90 is preferably made out of a highly conductive material that is in intimate contact with the backside of the substrate 84. The backing also protects the circuitry and light sources, protects the patient from electrical current and provides added padding to enhance patient comfort.

As will be apparent from the variations in construction that follow, numerous combinations of the interface and backing are possible. Because of the numerous configurations that the illuminator can take, as seen for example in Figures 3-5, there is no single optimum construction, but rather the functional characteristics described above are desirably provided in the most cost-effective manner for the particular application. Thus, for example, if the illuminator is to be used as a mat, as seen in Figure 4, additional padding between the substrate 84 and light-generating sources 76 may be required, which will increase the thickness of the interface and/or backing. Similarly, for an elongated pad-type illuminator, as seen in Figures 2-3 and 5, padding is not as important as the illuminator being flexible and lightweight. Additionally, the contact surface of the illuminator must be relatively soft and preferably hypoallergenic if it is to be used for treatment of hyperbilirubinemia in neonates.

The illuminator may be formed into a variety shapes, such as a pad or mat shown. Alternatively, the illuminator can be formed into a belt, a wrap, a cushion or pillow, a collar, a blanket, a strap, a vest, or any other desired shape. Advantageously, the particular shape and ultimate configuration on the patient does not affect the quality and intensity of the light delivered, as with prior fiber

optic devices.

Light Diffusion

At least a portion of the interface preferably causes the light emitted by the plurality of light-generating sources to be diffused or directed as desired. Such diffusion or direction is effective to provide a more uniform, constant and intense light pattern on the contact surface relative to a similar apparatus including a plurality of discrete light emitting sources without light diffusion. Therefore, the interface may be made of a single material or blend of materials having different refractive indices, such as silicone and glass bubbles or silicone and titania. Thus, in Figure 7, the front cover 72 comprises a matrix of silicone within which a plurality of glass bubbles is randomly impregnated. Figure 8 illustrates a cover 112 which comprises a matrix of silicone having a plurality of more evenly distributed glass bubbles 111. It should be noted that the size of the glass bubbles in the figures is exaggerated for illustration purposes. Alternatively, or in addition, the covering 72 or 112, or the insulating layer 110, may be provided with deformities or markings formed by mechanical, chemical, or other means to cause light emitted by the light-generating sources to diffuse. Such deformities or markings can be formed by molding, cutting, hot stamping, etching, painting, machining, coating, forming, milling, or printing. The deformities may vary in density, opacity, shape, color, index of refraction, size, depth and shade so as to produce a desired diffusion or light distribution. In one embodiment, such surface deformities are created by roughening the surface of the cover mold with glass beads or sand so as to give the surface a matte finish. The interface, such as the covering, may vary in color, index of refraction, or shape along the length of the

illuminator. A reflector or reflectors may be used to diffuse light. Lambertian reflectors also can be used. Prismatic films and diffusers, lenticular lenses, coatings, and other systems or materials may be used to cause light to be diffused as desired. Reflective paints or coatings, such as coatings of magnesium oxide, aluminum oxide, other white powders and the like and mixtures thereof, are useful for diffusion.

Figures 17, 17A, 17B, 17C and 17D illustrate the use of such paints or coatings. An LED 504 is shown positioned relative to a light reflecting surface 506 of illuminator 510 in accordance with the present invention. Reflecting surface 506 can be a metallized surface or a surface with a matte finish or the like. Contact surface 512 is part of the interface of illuminator 510 and is spaced apart from LED 504. Arc 514 is a representation of the intense light pattern on contact surface 512 generated by LED 504 with no light diffusion. The light within arc 514 is very intense while the light from LED 514 outside the arc is substantially less intense and may not be therapeutically effective.

Figure 17A illustrates a pattern of white dots 520 that can be painted or coated on contact surface 512 within the arc 514 to diffuse the intense light. The diameter of the dots decreases from the center of the pattern outwardly. This pattern of dots 520 scatters and/or reflects some of the light back to the reflecting surface 506. The pattern of dots depends, for example, on the thickness of the layer on which the contact surface is located and its distance from LED 504, and the presence of any additional light diffusing material or materials in the interface. The pattern of dots 520 results in a substantially more diffuse, yet therapeutically effective light pattern on the contact surface 512.

Figures 17B, 17C and 17D illustrate alternate coating

patterns that can be used in place of dots 520. Thus, a pattern of rectangles 522, a pattern of outwardly radiating lines 524 or a series of circles 526 can be used in much the same way as dots 520 to provide for enhanced light diffusion.

The interface may also comprise filters to reflect or absorb certain wavelengths of light. In order to control the exposure of the patient to ultraviolet radiation, or to minimize the deteriorative effect of such radiation on the illuminator, a layer or coating of or containing an ultraviolet absorber may be used. For example, the insulating layer 110 shown in Figure 8 may instead represent an ultraviolet filter. Examples of ultraviolet absorbers include bezophrenones, benzotriazoles, and salicylates. In addition, the illuminator made further comprise additives, including infrared absorbers (e.g., metals), antioxidants, coloring agents, plasticisizers, stabilizers, and antistatic agents.

Flexible Substrate

The present invention utilizes any type of flexible circuitry substrate known in the arts. Typically, the term "flexible substrate" pertains to polymeric sheets which may be bent or rolled without breaking. In one embodiment, the substrate may be said the flexible if it can be rolled, without breaking, into a cylindrical tube having a diameter less than 30 cm, and more preferably less than 5 cm. Examples of such flexible substrates are flexible printed circuitry laminates, which are composites of methyl conductors and dielectric substrates bonded together by an adhesive system. Other flexible substrates may not use adhesives, such as copper foil which is electrolytically deposited or rolled-annealed.

The substrates should be flexible and cable of withstanding the heat generated during the manufacturing

process and by the light-generating sources. Consideration should also be given to the dimensional stability, chemical resistance, electrical properties, flame retardancy, and cost. Substrates can be either thermosetting or thermoplastic polymers, such as polyester and polyimide films.

If an adhesive is used to secure the conductive tracings to the substrate, consideration should be given to the thermal properties of the adhesive. Desirably, the adhesive is highly heat conductive to further facilitate conduction of the heat generated by the light-generating sources throughout the substrate and to adjacent heat sinks.

The flexible substrate may comprise a reflector on the side facing the contact surface for directing light from the light-generating sources toward the contact surface. The reflector may be a thin, flexible sheet adhered to the flexible substrate. Alternatively, the reflector may be comprised of reflective materials coated directly on the flexible substrate. The reflector is desirably perforated in the locations of the light-generating sources and may be coated to reflect an appropriate wavelength or range of wavelengths of light. The reflective materials may be metals such as aluminum, silver or gold (or alloys thereof), or dielectrics coated at thicknesses designed to reflect desired wavelengths, or reflective paint. In one embodiment, the reflector provides lambertian reflectance, for example, reflects light by using a paint or coating which is white or matches the color of the LEDs.

Conductive Tracings

The flexible substrate may be coated, cast, deposited, or otherwise adhered to the conductive tracings or vice versa. In a preferred embodiment, the conductive tracings are directly adjacent to and in contact with the flexible

substrate. Alternatively, one or more additional layers may be present between the conductive traces and flexible substrate, such as when adhesives are used. The conductive tracings may be a variety of materials, including rolled-annealed copper, electro-deposited copper, silver, gold, aluminum, iron, steel, solder, or any other metal or conductor. The conductive coating may be applied as, or processed into, tracings using any means for application or removal, including chemical, mechanical, and optical means, as well as the use of lasers. In a preferred embodiment, a plurality of pairs of parallel conductive traces are etched into the rolled-annealed copper coating of a flexible substrate, for example, using conventional photo-etching techniques.

Polymer thick films including one or more finely divided conductive materials like silver, nickel, or carbon in a polymer binder like polyester, epoxy, acrylic, or vinyl also may be used. Polymer thick film printed wiring is less expensive than copper conductors since it is generally formed in a single step using screen printing, without traditional plating, etching, stripping, and cleaning. Examples of polymer thick films which offer an alternative to other types of circuitry are available from Du Pont as the CB® series polymer thick film pastes.

An insulating film or coating may be applied over the conductor surface to protect the circuitry for moisture, contamination, and conductor damage, and to reduce stress on the conductors during flexing. These protective coatings may be overlays comprising an insulating film coated with an adhesive, a coating comprising liquid polymers applied to the circuit, leaving the pad areas exposed, and solder masks comprising film laminates into which conductor access holes have been formed. Adhesives such as epoxies and polyimide resins may be used for overlays and laminations.

Light-generating Sources

The light-generating sources are preferably a light-emitting diode (LED) chip or die of the surface mount variety. Alternatively, other types of LEDs, lasers, and laser diodes also may be suitable. The light-generating sources may be multicolored LEDs, or a combination of multiple colored LEDs, a combination of different LEDs, or arrangement of the same type of LEDs, depending on the desired color, distribution or pattern.

For the treatment of neonatal hyperbilirubinemia, the preferred color of LEDs is blue, although green LEDs also may be effective. The treatment of other conditions may require different colored LEDs. For example, herpes may be most effectively treated by red LEDs, seasonal affective disorder may be treated by white or yellow LEDs, and psoriasis may be treated by ultraviolet LEDs.

The illuminator of the present invention may include any suitable interconnection technology to provide an electrical circuit among the LEDs, the substrate, the power supply, and any control device. In this regard, flexible or traditional wiring, solder attachment, conductive pieces, and/or pressure connectors may be used. A preferred embodiment utilizes surface mount technology to adhere the light-generating sources to the flexible substrate. Such manufacturing technologies may comprise surface mount-on-flex (SMT), chip-on-flex (COF), flip chip-on-flex (FCOF), micro-surface mount technology (micro SMT), micro-ball grid array (micro BGA), controlled collapsed chip connection (C4), or any known method of manufacture or assembly.

Illuminator Control

The illuminator may comprise a controller capable of making the light-generating sources separately addressable so that they may be selectively illuminated in a particular

pattern to achieve a particular therapeutic result. In addition, the power level of one or all of the light-generating sources may be controlled to optimize the light intensity required, to mix colors where different LEDs are used, or to shut off light-generating sources in the case of overheating. In the latter instance, thermocouples may be provided in and around the light-generating sources, or on the contact surface, to monitor the temperature of the illuminator and provide feedback to the controller. Finally, the illuminator controller may contain a timer to assist in metering exposure of the patient according to doctor's instructions.

Cooling Means

The interface of the illuminator preferably occupies the space between the substrate and the external contact surface. The interface may contain fins, vanes, ridges, grooves, tubes, holes, channels, or other features to absorb or diffuse heat, to increase surface area for heat exchange, and/or to control or direct a flow of air, water or other fluids. Alternatively, the interface may be solid if heat is not a concern.

As will be apparent from the structural variations shown herein, the illuminator may include holes or spaces through the substrate, covering, or between the covering and substrate in locations which avoid interference with the conductive traces, light sources, and cooling fluids. The illuminator may utilize air or water, and an associated blower or pump to force the cooling fluid through spaces.

The interface may be made of silicone, urethane, polyurethane, or any flexible plastic or other translucent or transparent material, or colored material, and combinations thereof. As mentioned above, silicone with at least a portion having glass bubbles and/or titania impregnated therein is preferred.

Disposable Overwrap

The illuminator is desirably at least partly surrounded with a disposable overwrap as a contamination barrier between the illuminator and the skin of the patient. Such an overwrap may be thin polyethylene or cellophane, for example, and is preferably transparent so as not to interfere with the transmission of light to the patient. The overwrap is preferably loosely fitted over the illuminator in any form, and can be easily secured by tape or other means and removed for sanitary purposes and subsequent immediate re-use of the illuminator.

Alternative Illuminator Constructions

Figures 11-13 illustrate various cross-sections of illuminators in accordance with present invention showing the basic elements of a substrate, a light-generating source (in this case an LED), an interface between the substrate to a contact surface, and a backing. Consistent with the discussion above regarding the functional characteristics, these variations are helpful in illustrating the multiple permutations of materials and configurations that are possible in constructing an illuminator of the present invention.

Figures 11A-11D illustrates four cross-sections that all have a substrate 160, an LED 162, and an interface comprising a solid layer 164 of light-diffusing and heat-insulating material. The layer 164 has an exterior skin contact surface 166. One example of material for the layer 164 is silicone having glass bubbles distributed randomly throughout. Another example of material for the layer 164 is silicone having titania distributed throughout. Alternatively, or in addition, the layer 164 may be silicone having a matte finish on the skin contact surface 166. The skin contact surface may have a pattern, for example, a printed pattern, effective to scatter and

diffuse light.

In Figure 11A, the backing comprises a solid layer 168 of light-reflective, heat-conductive material. Figure 11B includes a backing comprising a solid layer 170 of light-diffusive, heat-conductive material. In Figure 11C, the backing comprises a back cover 172 spaced from a substrate 160 with a secondary spacer 174. The secondary spacer 174 includes gaps or channels 176 therein directly across the substrate 160 from each of the LEDs 162. In Figure 11D, the backing comprises a back cover 178 spaced from the substrate 160 with a secondary spacer 180. In this case, the secondary spacer 180 is provided directly underneath each of the LEDs 162, and preferably is made of a highly heat conductive material. Heat thus flows from the LED 162 through the substrate to the secondary spacer 180, which is cooled on either side by the gaps 182.

Figures 12A-12F all include the substrate 160, LED 162, and a front cover 190 whose exterior surface is intended to contact the skin of patient. In addition, each of the cross-sections in Figures 12A-12F include one or more gaps or channels for cooling.

In Figure 12A, the cover 190 is spaced from the substrate 160 with a spacer 192. The spacer 192 is formed directly over the LEDs 162 and defines gaps or channels 194. The backing comprises a solid layer 196 of light-reflective, heat-conductive material. In Figure 12B, the interface includes the aforementioned spacer 192 and channels 194, as in Figure 12A, but the backing comprises a back cover 198 spaced from the substrate 160 with a secondary spacer 200. In this embodiment, the secondary spacer 200 provides gaps or channels 202 directly underneath each of the LEDs 162.

Figure 12C shows a spacer 204 separating the cover 190 from the substrate 160, the spacer 204 providing gaps or channels 206 directly surrounding each of the LEDs 162. In

this embodiment, the interface is formed by the cover 190, spacer 204, and channels 206, and the cooling medium can flow directly over each of the LEDs 162. Again, the backing is provided by a solid light-reflective, heat-conductive layer 208. Figure 12D also illustrates the spacer 204 and channel 206, which together with the cover 190 comprise the interface, but the backing is provided by a spacer 210 and a back cover 212. The spacer 210 is directly underneath each of the LEDs 162 and forms gaps or channels 214 therearound.

Figures 12E and 12F are substantial mirror images of one another, each of which having cooling channels above and below the substrate 160. In Figure 12E, the interface comprises the cover 190, the spacer 220 directly surrounding each of the LEDs, and gaps or channels 222 defined by the spacer. The backing comprises a secondary spacer 224 directly underneath each of the LEDs 162, a back cover 226, and a plurality of gaps or channels 228 adjacent the secondary spacer. In Figure 12F, a spacer 230 separates the cover 190 from the substrate 160 and defines cooling gaps or channels 232 directly over each of the LEDs 162. The backing comprises a secondary spacer 234 separating a back cover 236 from substrate 160 and defining a plurality of cooling gaps or channels 238 directly underneath each of the LEDs 162.

Figures 13A-13D illustrates several illuminator cross sections with maximum spaces defined by vanes or walls between two covers. More specifically, each of the cross-sections in Figures 13A-13D includes the substrate 160, LED 162, a front cover 250, and a back cover 252.

Figure 13A includes a plurality of vanes or walls 254 spacing the front cover 250 from the substrate 160. Cooling gaps or channels 256 are defined by the walls 254 surrounding each of the LEDs 162. The backing comprises the back cover 252 spaced from the substrate 160 by

secondary walls 258. Again, and gaps or channels 260 are provided below the substrate for cooling purposes.

In the embodiment of Figure 13B, walls 262 extend between the front cover 250 and a coating layer 264 provided on top of the substrate 160. The coating layer extends into contact with each of the LEDs 162. As in Figure 13A, the walls 262 defined gaps or channels 266 surrounding each of the LEDs 162. The backing comprises secondary walls 268 extending between the back cover 252 and a coating 270, and gaps 272 provided directly underneath each of the LEDs 162.

Figure 13C is similar to that shown in Figure 13B and includes walls 274 extending between the front cover 250 and a layer 276 formed on the substrate 160. In this case, the layer 276 completely covers each of the LEDs 162. Cooling gaps or channels 278 are formed over each of the LEDs, and the covering protects each of the LEDs from the corrosive effect of a fluid cooling medium. Also, as in Figure 13B, the backing comprises secondary walls 280 spacing the back cover 252 from a layer 282 formed on the backside of the substrate 160. Again, cooling gaps 284 are provided below each of the LEDs.

Finally, Figure 13D includes a spacer 290 extending between the substrate 160 and a front cover 250. The spacer 290 covers the substrate 160, as at 292, but provides gaps or channels 294 for cooling. The backing comprises a secondary spacer 296 extending between the substrate 160 and the back cover 252, the spacer being generally solid but defining gaps or channels 298 directly below each of the LEDs 162.

Passive Cooling

Up to now, various configurations of illuminators of the present invention have been described having internal gaps or channels, the understanding being that cooling

medium actively flows therethrough. While active cooling is certainly one option, a less-expensive variant is passive cooling. Figures 14A-14C illustrate three embodiments of an illuminator pad having passive cooling channels therethrough.

Figure 14A illustrates an illuminator pad 300 having a plurality of columns of apertures 302 extending from the front side to the back side. Preferably, the columns of apertures 302 are formed in between each column of LEDs 304 for maximum heat dissipation. Of course, the apertures should avoid interference with any copper tracings or light sources. Figure 14B illustrates an illuminator 306 having a series of channels 308 extending along the width dimension. The channels 308 are desirably formed between each column 310 of the LEDs. Finally, Figure 14C illustrate an illuminator 312 having a series of longitudinal channels 314 formed therein. In all of the embodiments seen in Figures 14A-14C, the apertures or channels are open at both ends and serve to passively dissipate heat generated by the LEDs.

Another configuration facilitating passive cooling is the use of external fins, as seen in Figures 15A-15C. In particular, Figure 15A illustrates an illuminator 320 having a plurality of fins 322 extending in the width dimension. In Figure 15C, the external fins 324 extend in the longitudinal dimension. Finally, in Figure 15C, the fins extend both in the width and longitudinal dimensions in a waffle pattern. Also, as shown in Figure 15A, the fins 322 are located on both the top and bottom surfaces of the illuminator. Of course, the fins, if present at all, can be located on the top and/or bottom surfaces of the illuminator. These fins provide passive cooling for the illuminators, and may be provided on the front or rear surfaces, or both.

A still further variation of passive cooling is seen

in the illuminator 340 of Figure 16. For illustration purposes, the cover 342 of the illuminator 340 is shown in phantom to reveal a plurality of pins or spacers 344 extending between the substrate 346 and cover 342. The side edges of the illuminator 340 remain open to permit passive cooling of the LEDs 348. Alternatively, the side edges may be closed and cooling medium flowed through conduit 350. In any event, the spacers 344 maintain a gap between the front cover 342 and the substrate 346 along the length of the illuminator 340.

While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced within the scope of the following claims.

WHAT IS CLAIMED IS:

1. An illuminator for delivering light energy to the skin of a patient for phototherapy, the illuminator comprising:

a thin, lightweight flexible substrate;

a plurality of conductive traces affixed to the substrate and being adapted to connect to an electrical power source;

at least one discrete light-generating source disposed on the substrate and coupled to the conductive traces; and

a covering at least partly surrounding the substrate and having an exterior surface that is spaced apart from the light-generating sources, the exterior surface being adapted to contact the skin of a patient.

2. The illuminator of claim 1, wherein the illuminator is sufficiently lightweight and flexible to be worn against the skin of a newborn infant without injury.

3. The illuminator of claim 1, which includes a plurality of discrete light-generating sources disposed on the substrate and coupled to the conductive traces.

4. The illuminator of claim 1, wherein the covering is configured to facilitate the effective dissipation of heat produced by the light-generating sources away from the skin of the patient.

5. The illuminator of claim 4, wherein the covering includes fins positioned to provide increased dissipation of heat produced by the light-generating sources away from the skin of the patient relative to a substantially identical covering without the fins.

6. The illuminator of claim 4, wherein the covering is spaced from the substrate and further including cavities between the covering and the substrate.

7. The illuminator of claim 1, wherein the covering at least partly defines an internal structure adapted to facilitate at least one of a) dissipation of heat produced by the light-generating sources away from the skin of the patient, and b) diffusion of light generally toward the skin of the patient.

8. The illuminator of claim 1, further including a reflector for reflecting light from the light-generating sources away from the substrate toward the patient.

9. The illuminator of claim 8, wherein the light-generating sources comprise surface mount LEDs, and the reflector comprises a thin, flexible sheet perforated with holes through which the LEDs project.

10. The illuminator of claim 1, further including cooling means for effectively dissipating heat generated by the light-generating sources so that the illuminator can safely and comfortably contact the skin of a patient.

11. The illuminator of claim 1, further including a disposable overwrap sized to at least partly surround the illuminator and provide a contamination barrier between the illuminator and the skin of the patient.

12. An illuminator for delivering light energy to the skin of a patient for phototherapy, the illuminator comprising:

a thin, lightweight substrate;

a plurality of conductive traces affixed to the

substrate and being adapted to connect to an electrical power source;

at least one light-generating source disposed on the substrate and coupled to the conductive traces; and

an interface at least partly covering the light-generating source on the substrate, the interface providing an effective heat transfer means to dissipate heat generated by the light-generating source so that the illuminator can safely contact the skin of a patient.

13. The illuminator of claim 12, wherein the illuminator is sufficiently lightweight to be worn against the skin of a newborn infant without injury.

14. The illuminator of claim 12, wherein the illuminator is flexible and adapted to conform to the skin of the patient.

15. The illuminator of claim 12, wherein the interface defines spaces between the covering and the substrate.

16. The illuminator of claim 15, wherein the spaces comprise channels for convective heat transfer.

17. The illuminator of claim 15, wherein there are a plurality of the light-generating sources, and the spaces are directly adjacent the light-generating sources.

18. The illuminator of claim 15, wherein the spaces are in communication with apertures provided through the substrate.

19. The illuminator of claim 12, wherein the interface comprises a insulating layer.

20. The illuminator of claim 12, further including means for passively cooling the light-generating source.

21. The illuminator of claim 12, further including means for active cooling of the light-generating source.

22. The illuminator of claim 12, wherein the illuminator defines a skin-contacting surface, the light-generating source has an intensity in excess of 50 microwatts, and the interface limits the maximum temperature of the skin-contacting surface to about 110°F.

23. The illuminator of claim 12, wherein the interface comprises a flexible, polymeric layer permitting light energy to penetrate therethrough and conforming to the skin of a patient.

24. An illuminator for delivering light energy to the skin for phototherapy, the illuminator comprising:

a thin, lightweight substrate;

a plurality of conductive traces affixed to the substrate and being adapted to connect to an electrical power source;

at least two discrete light sources disposed on the substrate and coupled to the conductive traces; and

an interface at least partly covering the light-generating sources on the substrate, the interface diffusing the light emitted from the discrete light sources, the illuminator being adapted to contact the skin of a patient.

25. The illuminator of claim 24, wherein the illuminator is sufficiently lightweight to be worn against the skin of a newborn infant without injury.

26. The illuminator of claim 24, wherein the interface comprises at least one material effective to diffuse light energy from the light source.

27. The illuminator of claim 24, wherein the interface comprises a blend of materials having different refractive indices.

28. The illuminator of claim 24, wherein the interface has an exterior surface adapted to contact the skin of a patient, the exterior surface being irregular to diffuse the light emitted from the discrete light sources.

29. The illuminator of claim 24, wherein the light sources are LEDs.

30. The illuminator of claim 24, further including a reflective backing in intimate contact with the substrate and comprising a heat conducting material.

31. The illuminator of claim 24, wherein the substrate comprises a print circuit board.

32. The illuminator of claim 44, further including a reflector for reflecting light from the light sources away from the substrate.

33. A wearable phototherapeutic illuminator for delivering light energy to the skin of a patient, comprising:

a flexible substrate;

at least one light-generating source disposed on the substrate; and

a flexible, polymeric layer covering the light-generating source, the layer permitting light energy to penetrate therethrough and adapted to substantially conform

to the skin of a patient.

34. The illuminator of claim 33, wherein the illuminator is sufficiently lightweight to be worn against the skin of a newborn infant without injury.

35. The illuminator of claim 33, wherein there are a plurality of the light-generating sources, the layer comprising a transparent matrix with glass bubbles dispersed therethrough to diffuse the light emitted from the light-generating sources.

36. The illuminator of claim 33, wherein there are a plurality of the light-generating sources, the layer comprising a blend of materials having different refractive indices to diffuse the light emitted from the light-generating sources.

37. The illuminator of claim 33, wherein there are a plurality of the light-generating sources, the layer having an exterior surface adapted to contact the skin of a patient, the exterior surface being irregular to diffuse the light emitted from the light-generating sources.

AMENDED CLAIMS

[received by the International Bureau on 26 December 2000 (26.12.00); original claims 1 – 37 replaced by amended claims 1 – 36 (6 pages)]

WHAT IS CLAIMED IS:

1. An illuminator for delivering light energy to the skin of a patient for phototherapy, the illuminator comprising:

a thin, lightweight flexible substrate;

a plurality of conductive traces affixed to the substrate and being adapted to connect to an electrical power source;

at least one discrete light-generating source disposed on the substrate and coupled to the conductive traces;

a reflector located on the substrate for reflecting light from the at least one light-generating source toward the patient; and

a covering at least partly surrounding the substrate and having an exterior surface that is spaced apart from the light-generating source, the exterior surface being adapted to contact the skin of a patient.

2. The illuminator of claim 1, wherein the illuminator is structured to be placed in contact with the skin of a newborn infant and used without injury.

3. The illuminator of claim 1, which includes a plurality of discrete light-generating sources disposed on the substrate and coupled to the conductive traces.

4. The illuminator of claim 1, wherein the illuminator is configured to facilitate the transfer of heat produced by the at least one light-generating source away from the skin of the patient sufficient to prevent such heat from adversely affecting the patient.

5. The illuminator of claim 4, wherein the illuminator includes at least one fin positioned to

light-generating sources away from the skin of the patient relative to a substantially identical illuminator without the fin.

6. The illuminator of claim 4, wherein the covering is spaced apart from the substrate and further comprising at least one cavity between the covering and the substrate.

7. The illuminator of claim 1, wherein the covering at least partly defines an internal structure adapted to facilitate at least one of a) dissipation of heat produced by the light-generating sources away from the skin of the patient, and b) diffusion of light generally toward the skin of the patient.

8. The illuminator of claim 7, wherein the internal structure is adapted to both a) dissipate heat produced by the light-generating sources away from the skin of the patient, and b) diffuse light generally toward the skin of the patient.

9. The illuminator of claim 1, wherein the light-generating source comprises an LED, and the reflector comprises a thin, flexible sheet perforated with holes through which the LED projects.

10. The illuminator of claim 1, further including cooling means for transferring heat generated by the at least one light-generating source so that the illuminator can safely and comfortably contact the skin of a patient.

11. The illuminator of claim 1, wherein the exterior surface is defined by a disposable overwrap sized to at least partly cover the illuminator and provide a contamination barrier between the illuminator

and the skin of the patient.

12. An illuminator for delivering light energy to the skin of a patient for phototherapy, the illuminator comprising:

a thin, lightweight substrate;

a plurality of conductive traces affixed to the substrate and being adapted to connect to an electrical power source;

at least one light-generating source disposed on the substrate and coupled to the conductive traces; and

an interface at least partly covering the light-generating source on the substrate, the interface providing heat transfer means for passively or actively cooling the light-generating source and transferring heat generated by the light-generating source so that the illuminator can safely contact the skin of a patient.

13. The illuminator of claim 12, wherein the illuminator is flexible and adapted to conform to the skin of the patient.

14. The illuminator of claim 12, wherein the interface defines spaces between the covering and the substrate.

15. The illuminator of claim 14, wherein the spaces comprise channels for convective heat transfer.

16. The illuminator of claim 15, wherein the heat transfer means actively cools the at least one light-generating source by convection using the channels.

17. The illuminator of claim 14, wherein there are a plurality of the light-generating sources, and the

spaces are adjacent to the light-generating sources.

18. The illuminator of claim 14, wherein the spaces are in communication with apertures provided through the external surface of the illuminator.

19. The illuminator of claim 12, wherein the interface comprises a thermal insulating layer.

20. The illuminator of claim 12, further including diffusing means for diffusing light emitted from the at least one light-generating source.

22. The illuminator of claim 12, wherein the interface comprises a flexible, polymeric layer permitting light energy to penetrate therethrough and conforming to the skin of a patient.

23. An illuminator for delivering light energy to the skin for phototherapy, the illuminator comprising:

a thin, lightweight substrate;

a plurality of conductive traces affixed to the substrate and being adapted to connect to an electrical power source;

at least one discrete light-generating source disposed on the substrate and coupled to the conductive traces; and

an interface at least partly covering the light-generating source on the substrate, the interface comprises a combination of at least two materials having different refractive indices so as to diffuse the light emitted from the discrete light-generating source, the illuminator being adapted to contact the skin of a patient.

24. The illuminator of claim 23, wherein the interface has an exterior surface adapted to contact the

skin of a patient, the exterior surface having surface deformities to diffuse the light emitted from the at least one discrete light-generating source.

25. The illuminator of claim 23, wherein the interface further provides heat transfer means for passively or actively cooling the light-generating source and transferring heat generated by the light-generating source so that the illuminator can safely contact the skin of a patient.

26. The illuminator of claim 23, further including a reflector for reflecting light from the at least one discrete light-generating source toward the patient.

27. The illuminator of claim 26, wherein the reflector is a diffusive reflector.

28. The illuminator of claim 27 wherein the diffusive reflector has a Lambertian (random) reflecting surface.

29. The illuminator of claim 23, wherein the interface has an exterior surface adapted to contact the skin of a patient, the exterior surface being irregular to diffuse the light emitted from the discrete light sources.

30. The illuminator of claim 23, wherein the at least one discrete light-generating source is an LED.

31. The illuminator of claim 23, further including a reflective backing in intimate contact with the substrate and comprising a heat conducting material.

32. The illuminator of claim 23, wherein the substrate comprises a print circuit board.

33. A wearable phototherapeutic illuminator for delivering light energy to the skin of a patient, comprising:

a flexible substrate;

a plurality of light-generating sources disposed on the substrate; and

a flexible, polymeric layer covering the light-generating sources, the layer permitting light energy to penetrate therethrough and adapted to substantially conform to the skin of a patient, the layer diffusing the light emitted from the sources to result in a more uniform overall emittance, the illuminator being adapted to contact the skin of a patient.

34. The illuminator of claim 33, wherein the layer comprises a matrix with glass bubbles dispersed therein to diffuse the light emitted from the light-generating sources.

35. The illuminator of claim 33, wherein the layer comprises a matrix with titania dispersed therein to diffuse the light emitted from the light-generating sources.

36. The illuminator of claim 33, wherein the layer comprises an exterior surface adapted to contact the skin of the patient, the exterior surface having surface deformities to diffuse the light emitted from the light-generating sources.

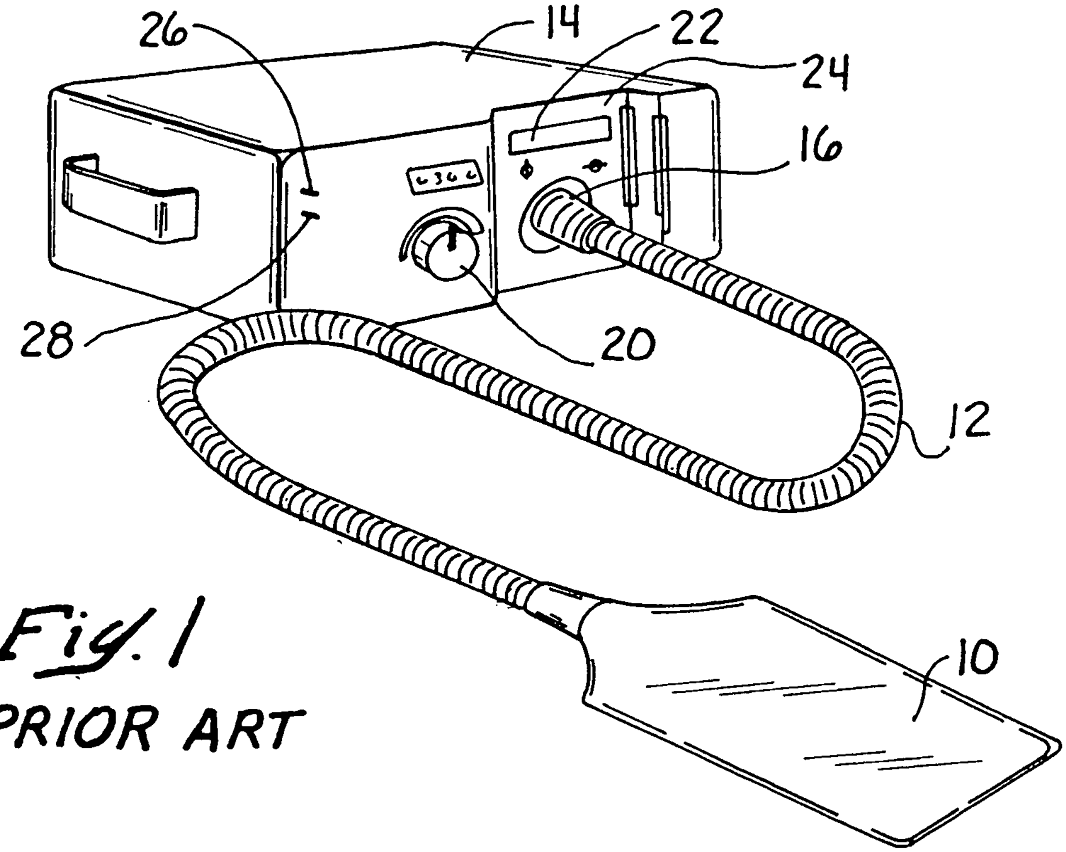


Fig. 1
PRIOR ART

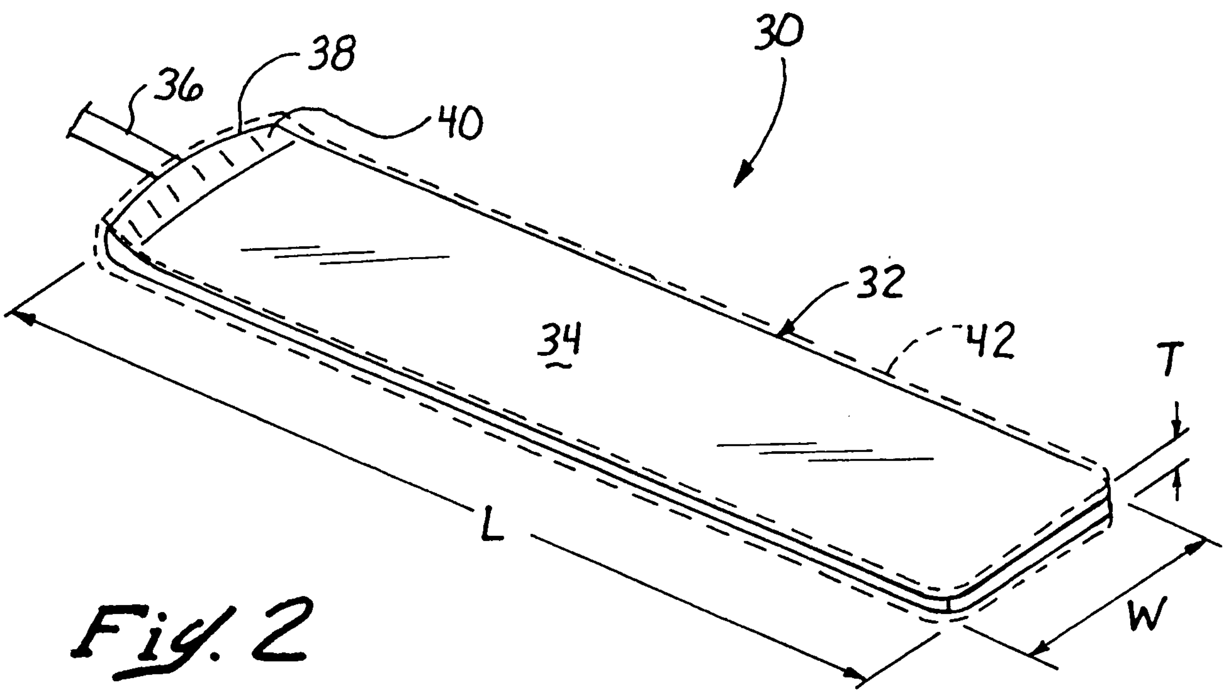


Fig. 2

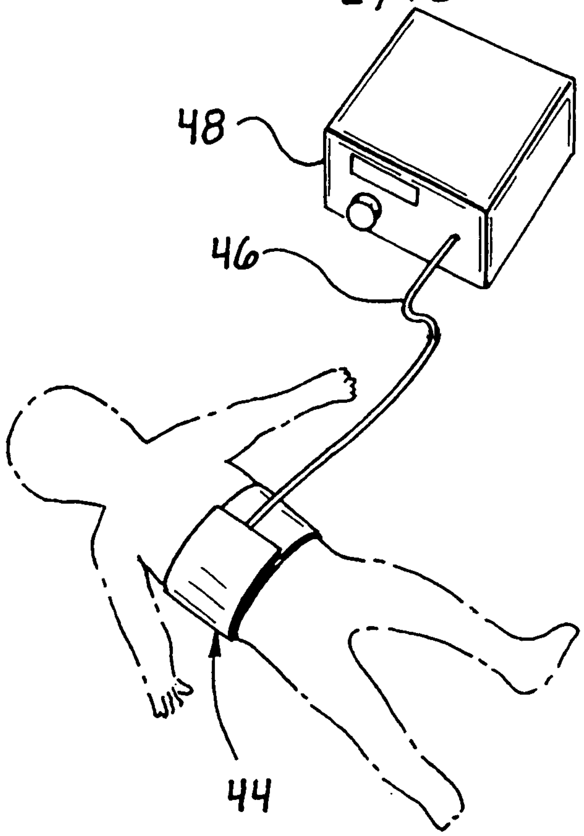

48
46
44

Fig. 3

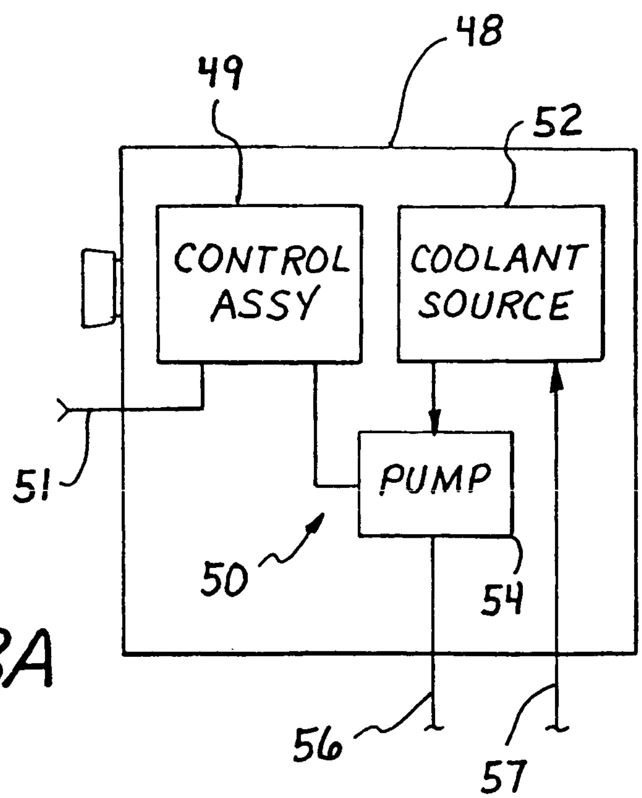

48
49
52
CONTROL ASSY
COOLANT SOURCE
PUMP
51
50
54
56
57

Fig. 3A

Fig. 4

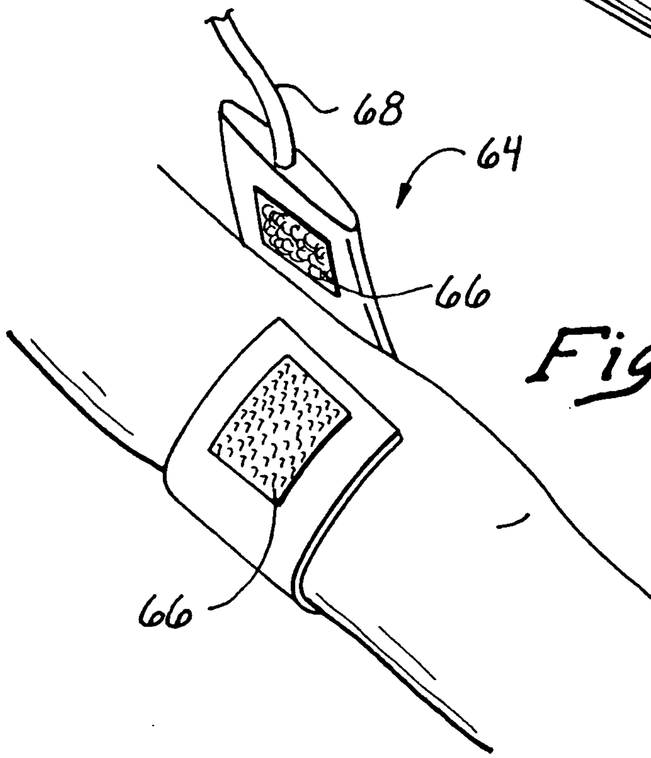


Fig. 5

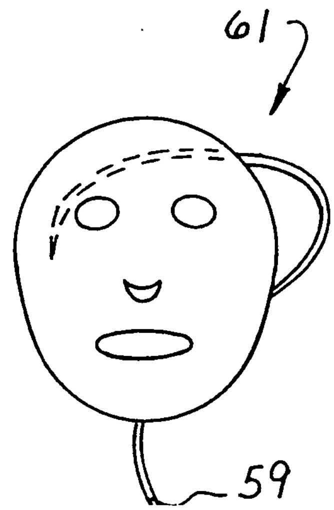


Fig. 5A

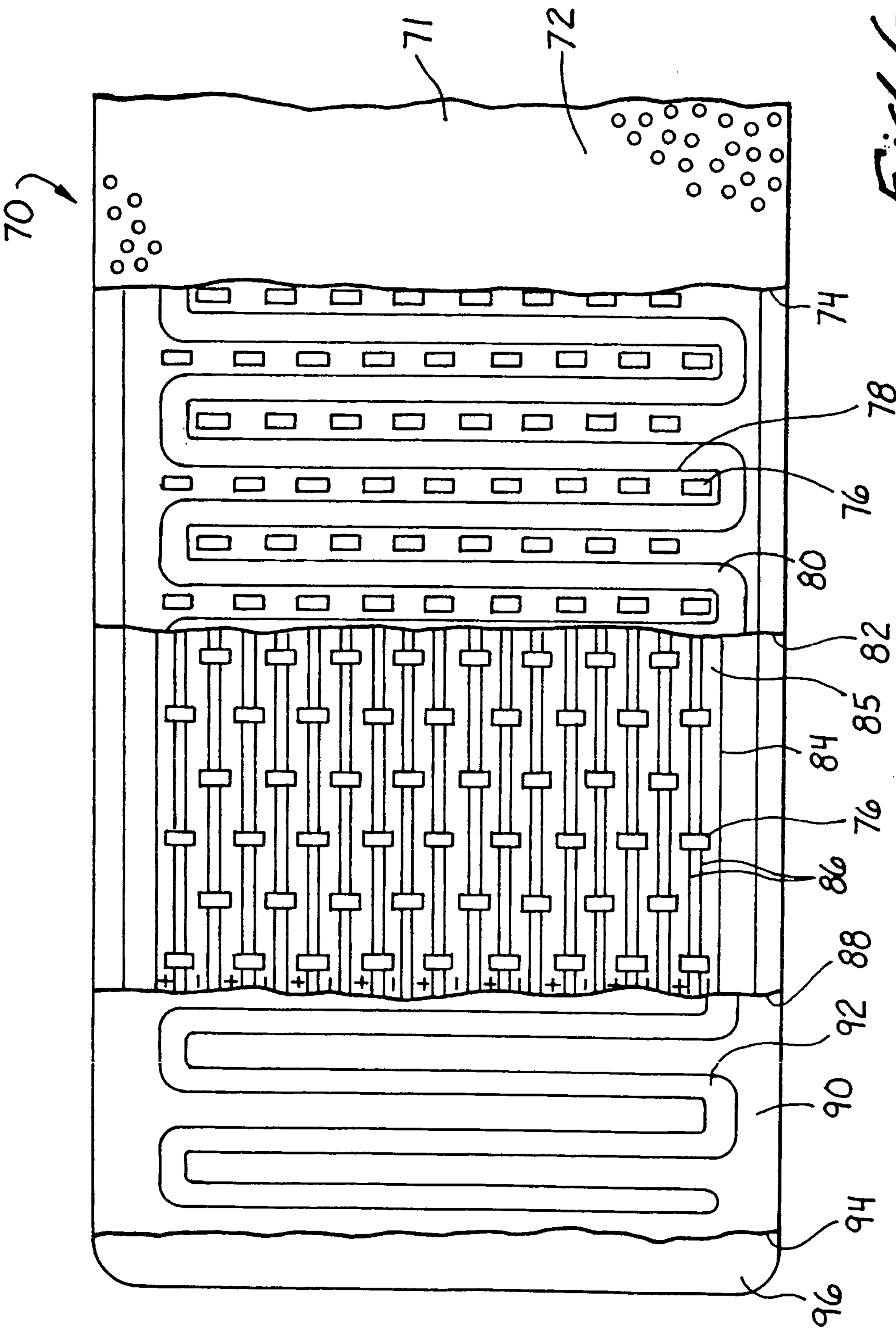


Fig. 6

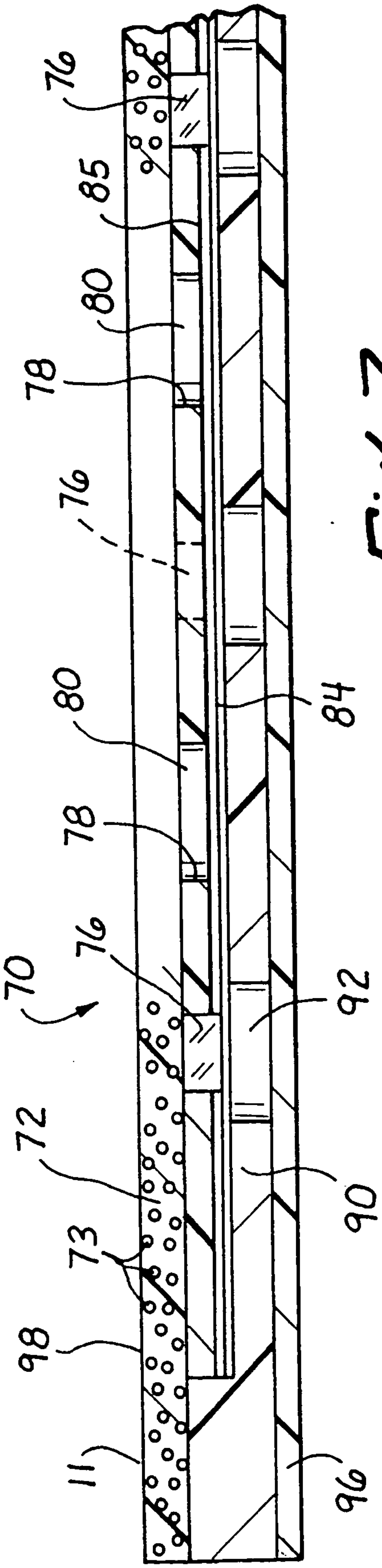

76
85
80
78
76
80
84
78
76
70
92
72
73
90
98
11
96

Fig. 7

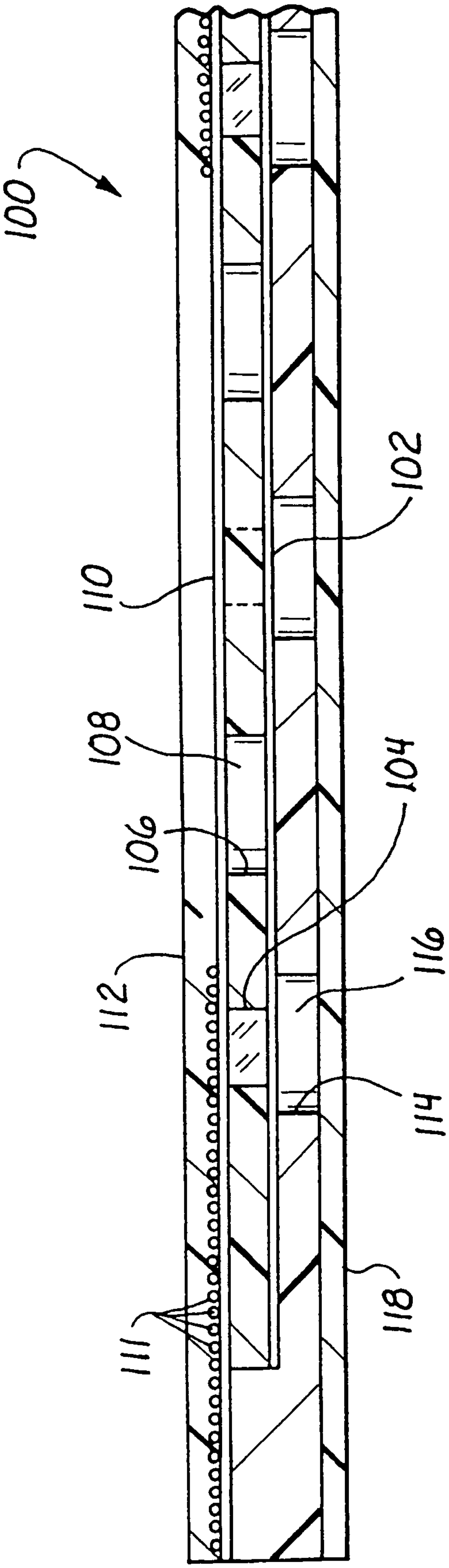

100
102
110
108
104
106
116
112
114
118
111

Fig. 8

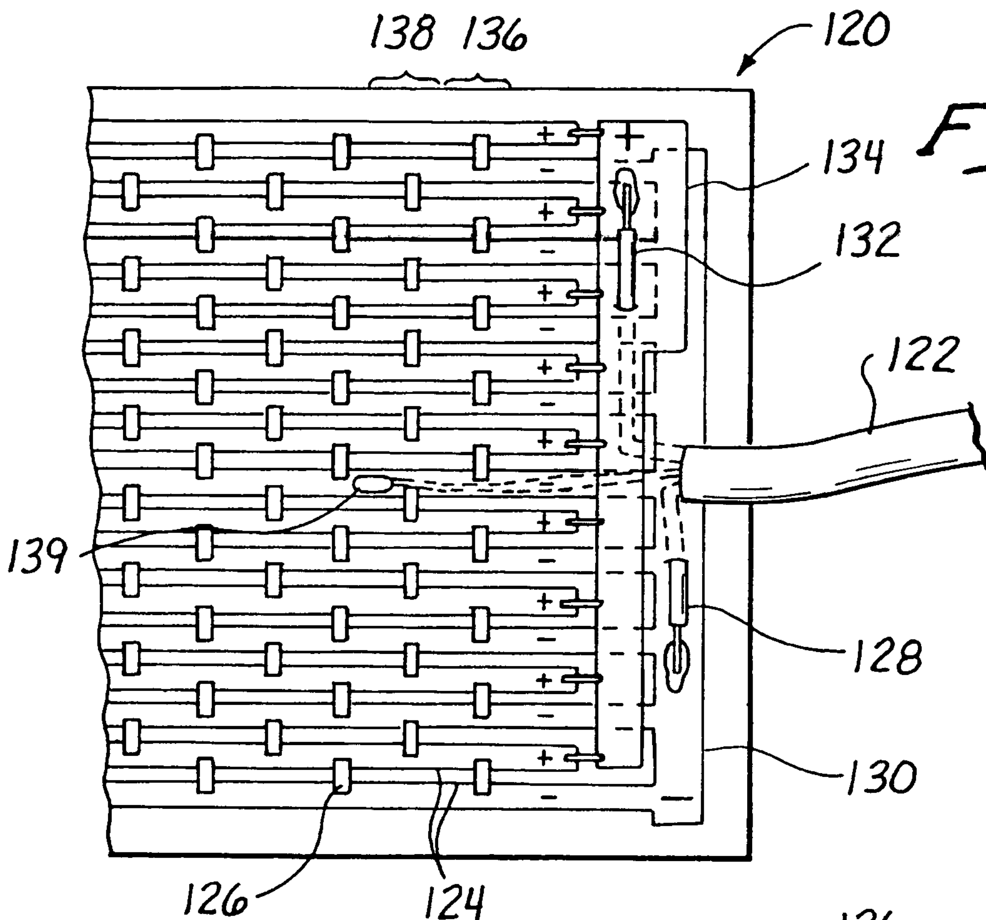

138
136
120
134
132
122
139
128
130
126
124
+
-

Fig. 9

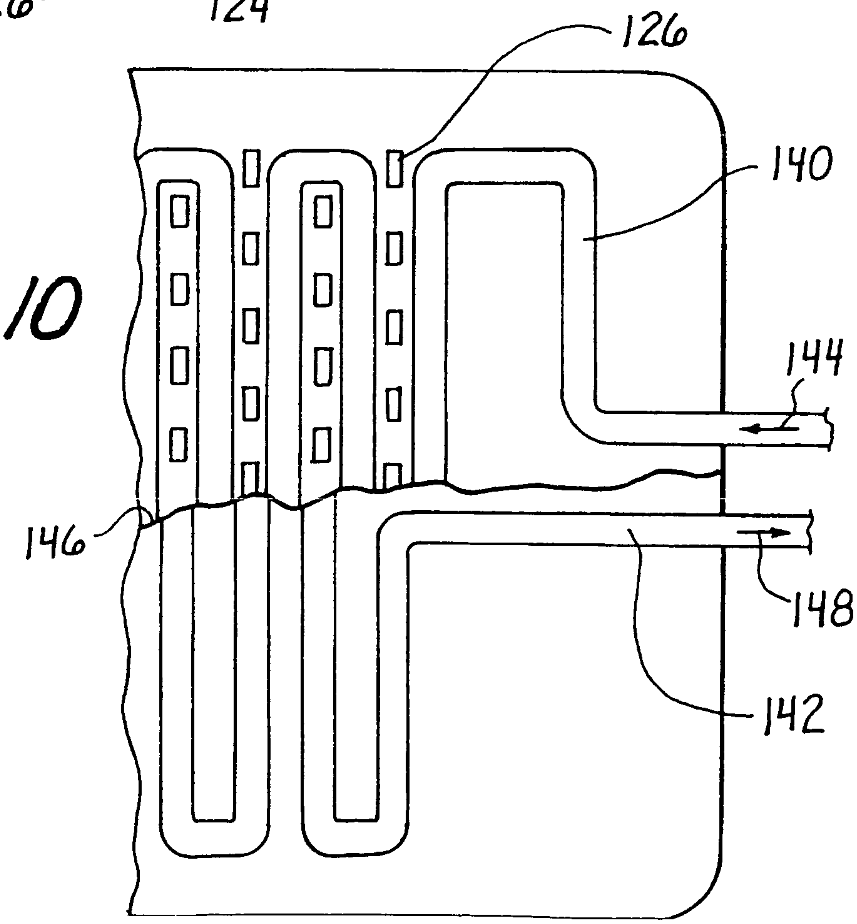

126
140
144
146
148
142

Fig. 10

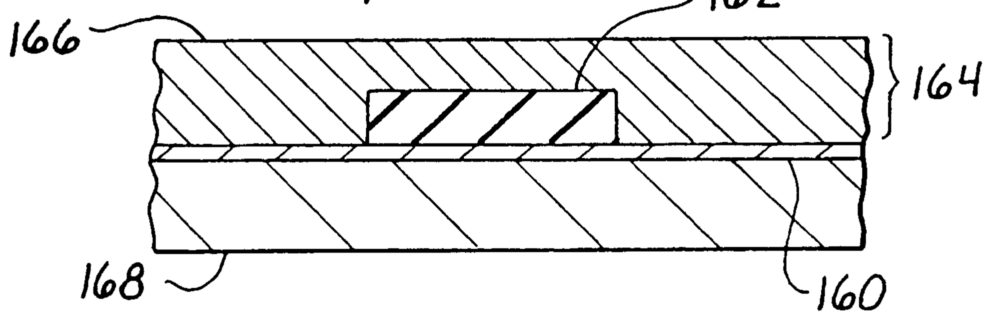


Fig. 11A

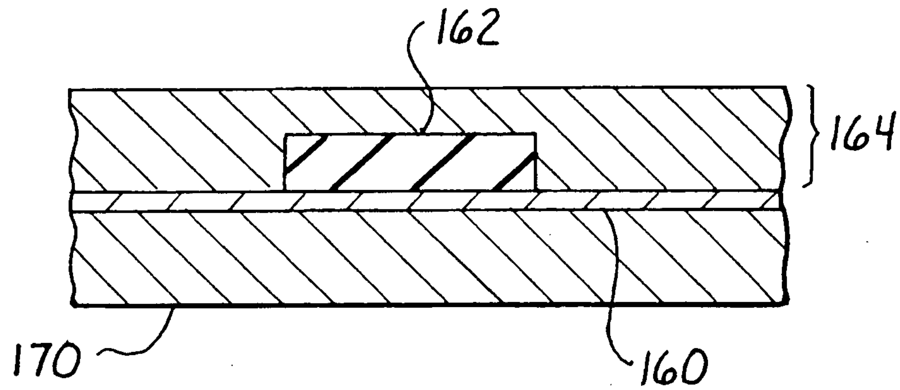


Fig. 11B

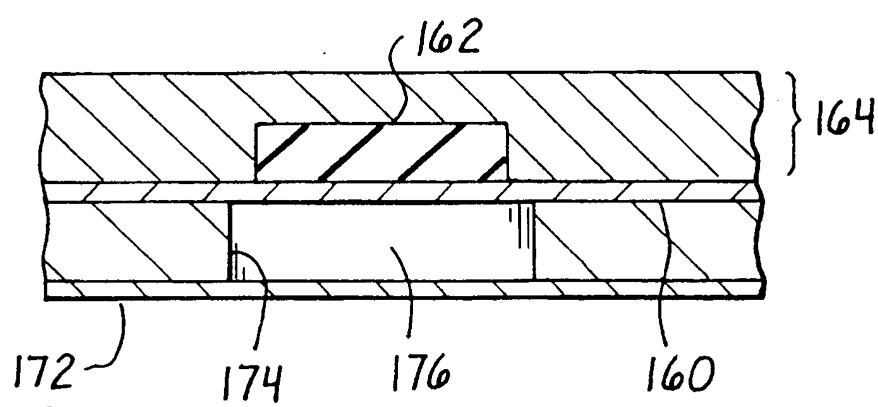


Fig. 11C

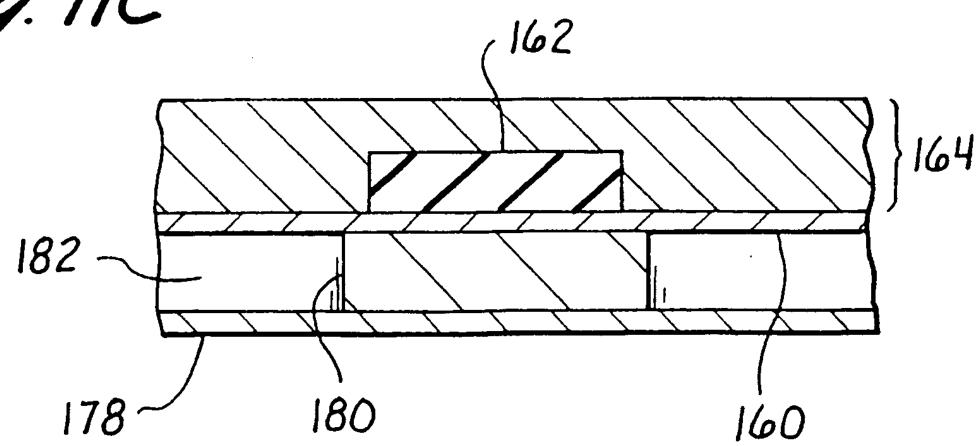


Fig. 11D

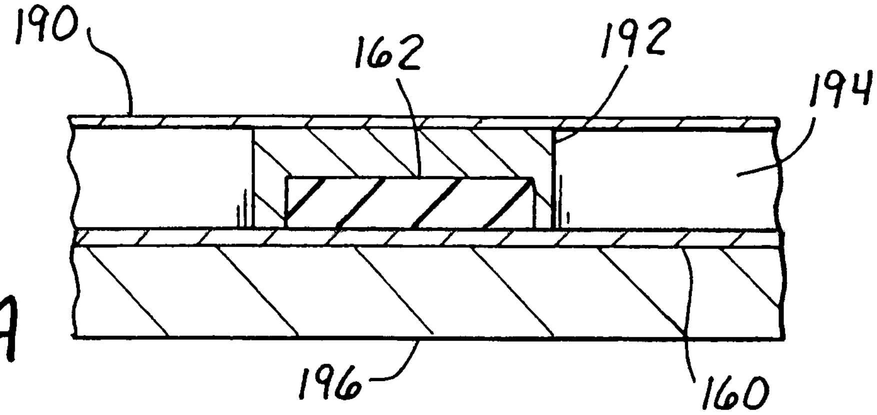


Fig. 12A

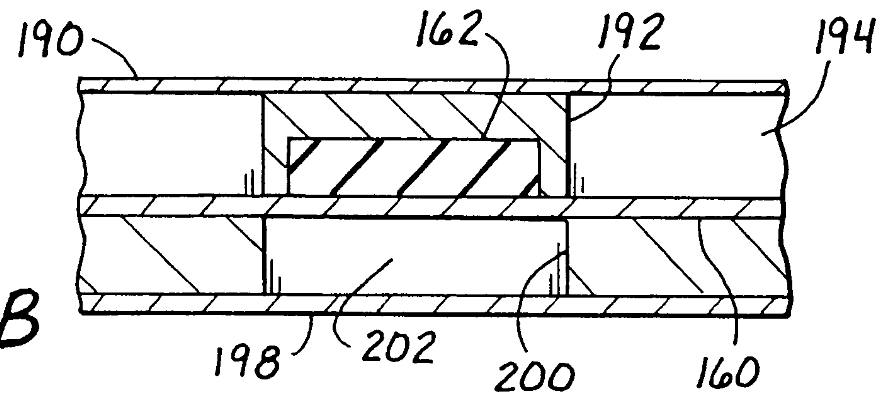


Fig. 12B

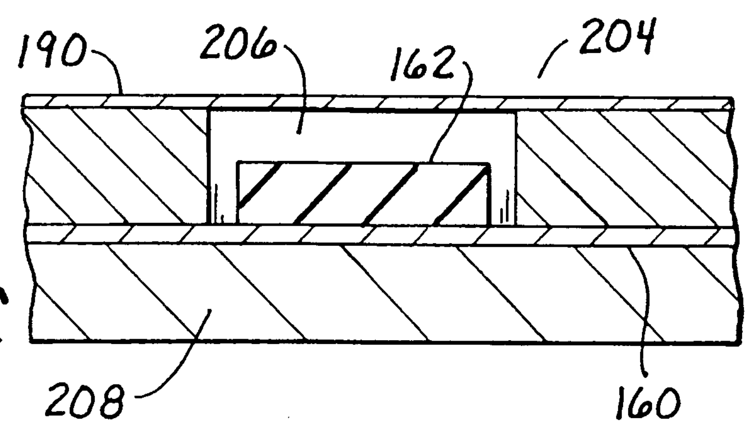


Fig. 12C

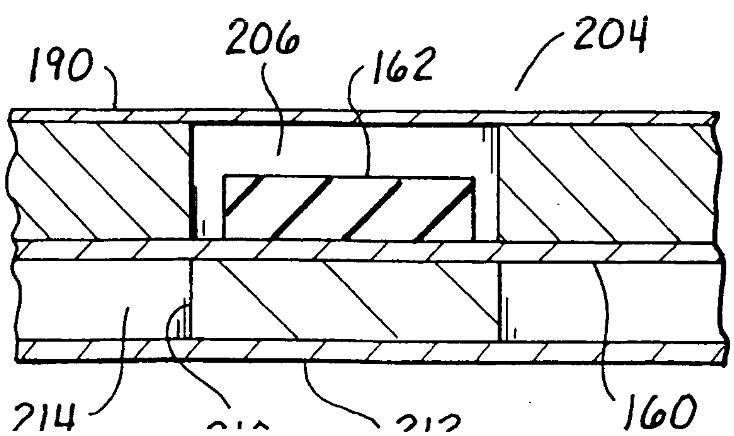


Fig. 12D

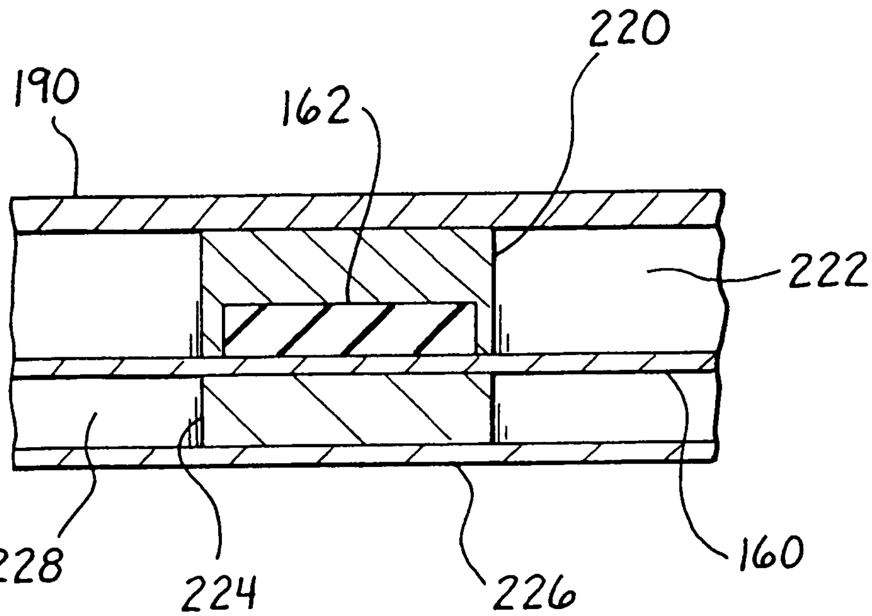


Fig. 12E

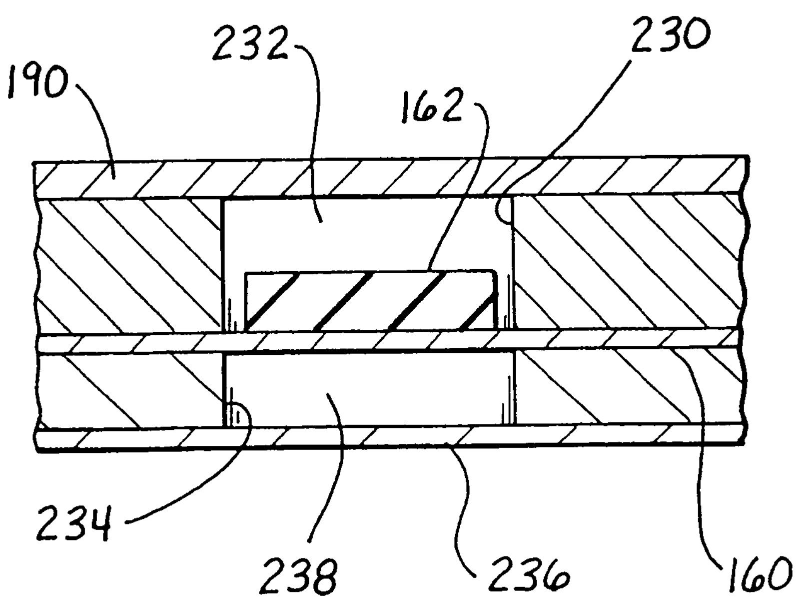


Fig. 12F

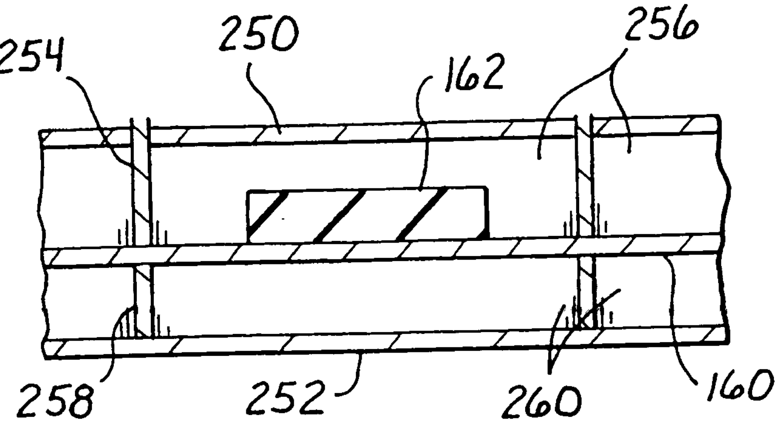


Fig. 13A

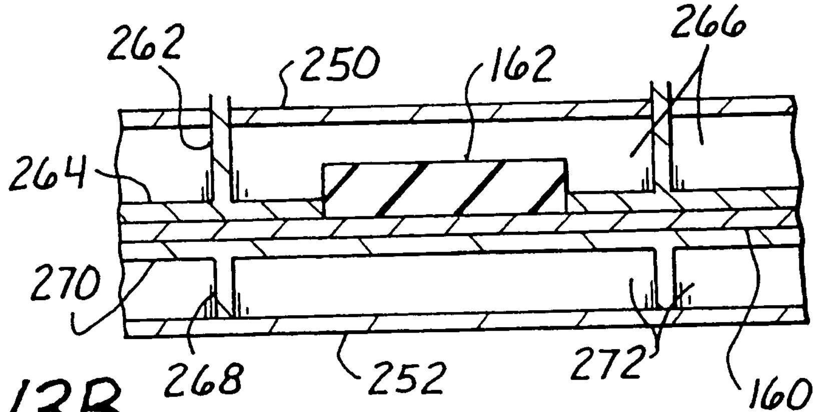


Fig. 13B

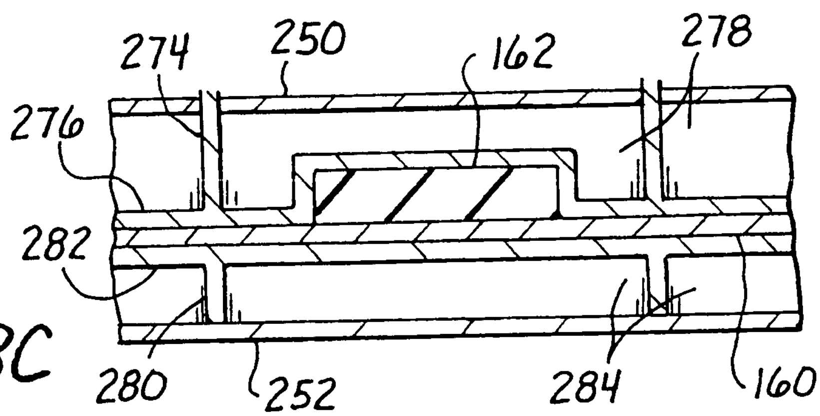


Fig. 13C

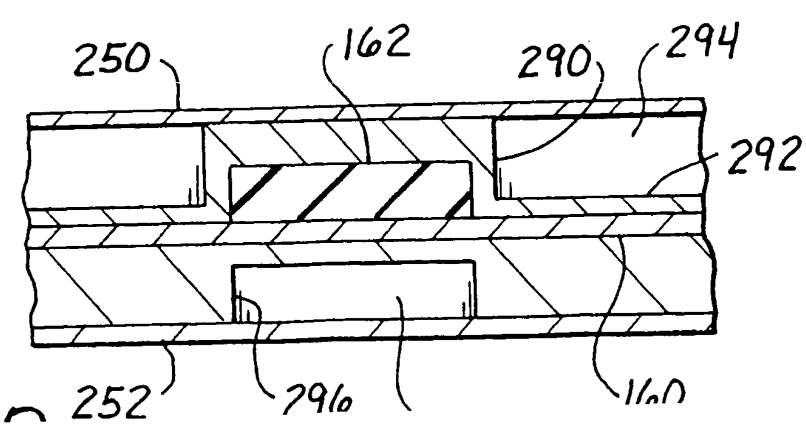


Fig. 14A

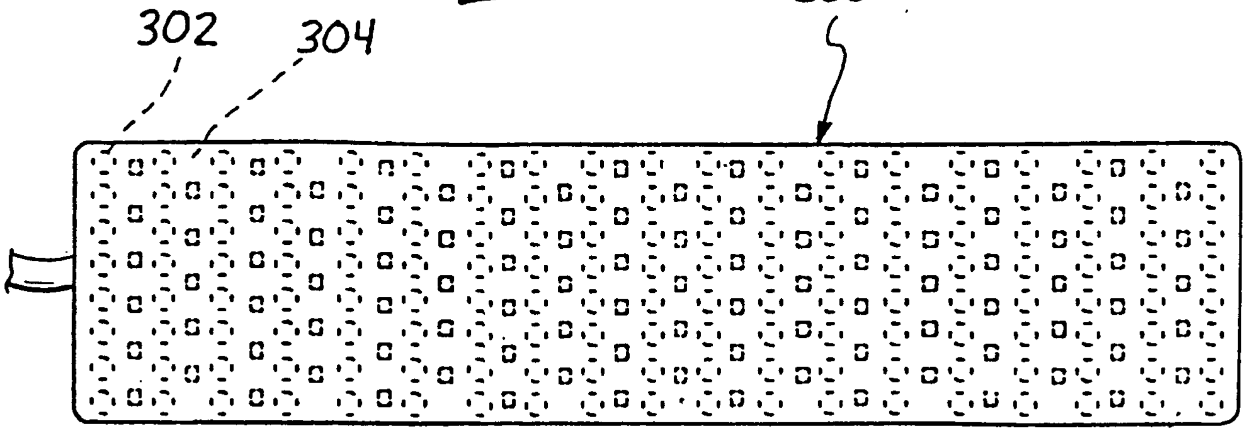


Fig. 14B

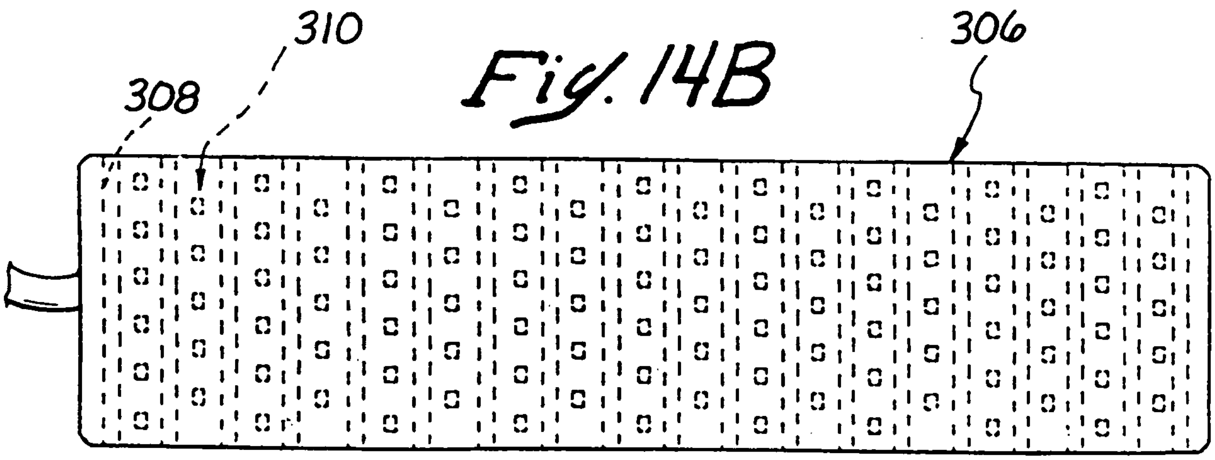
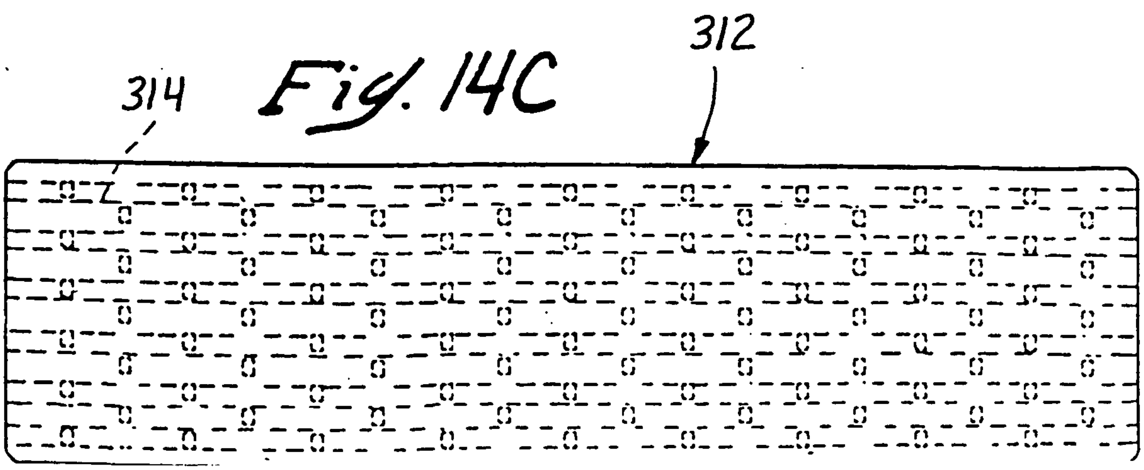


Fig. 14C



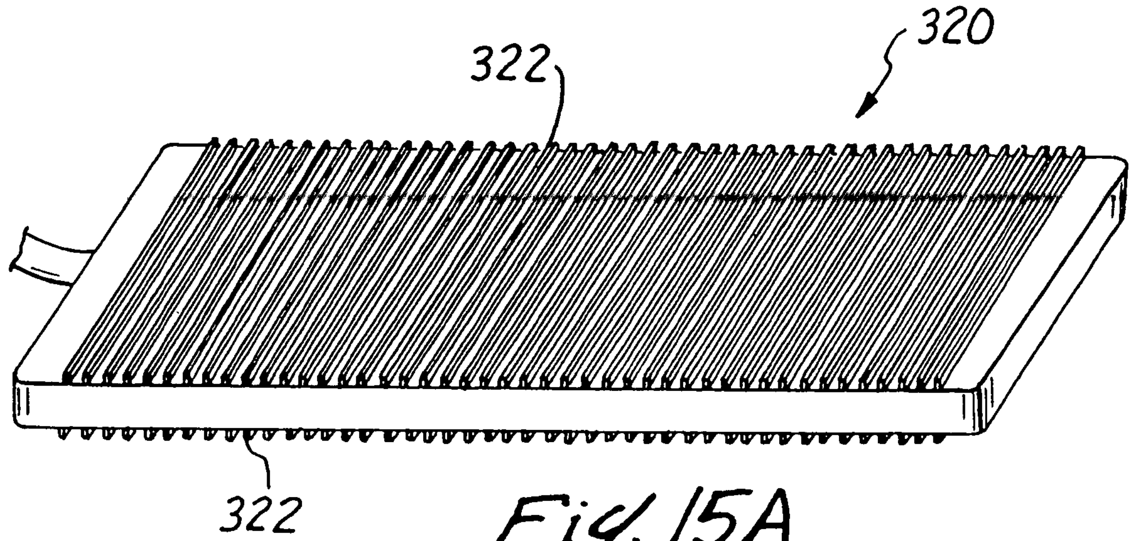


Fig. 15A

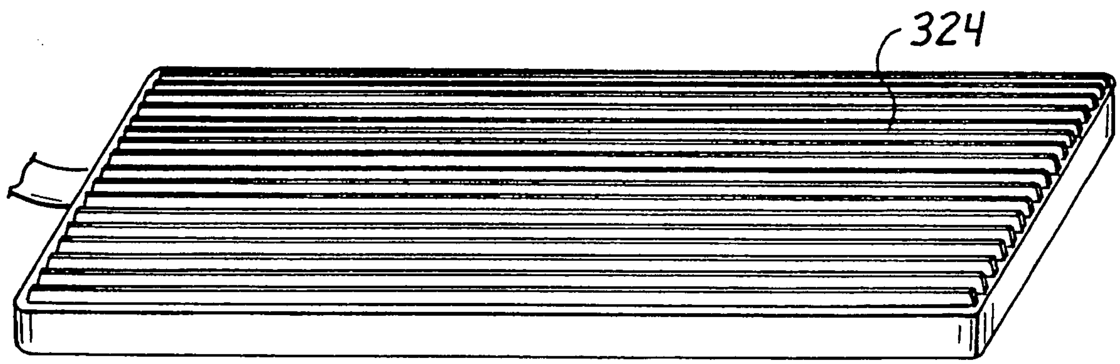
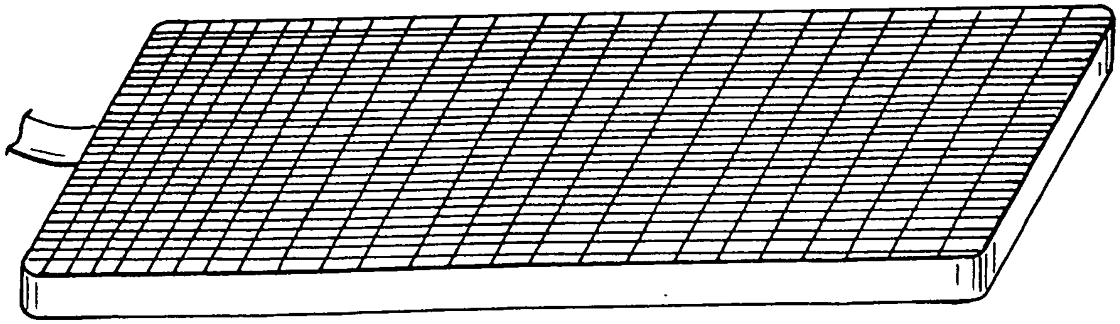


Fig. 15B

Fig. 15C



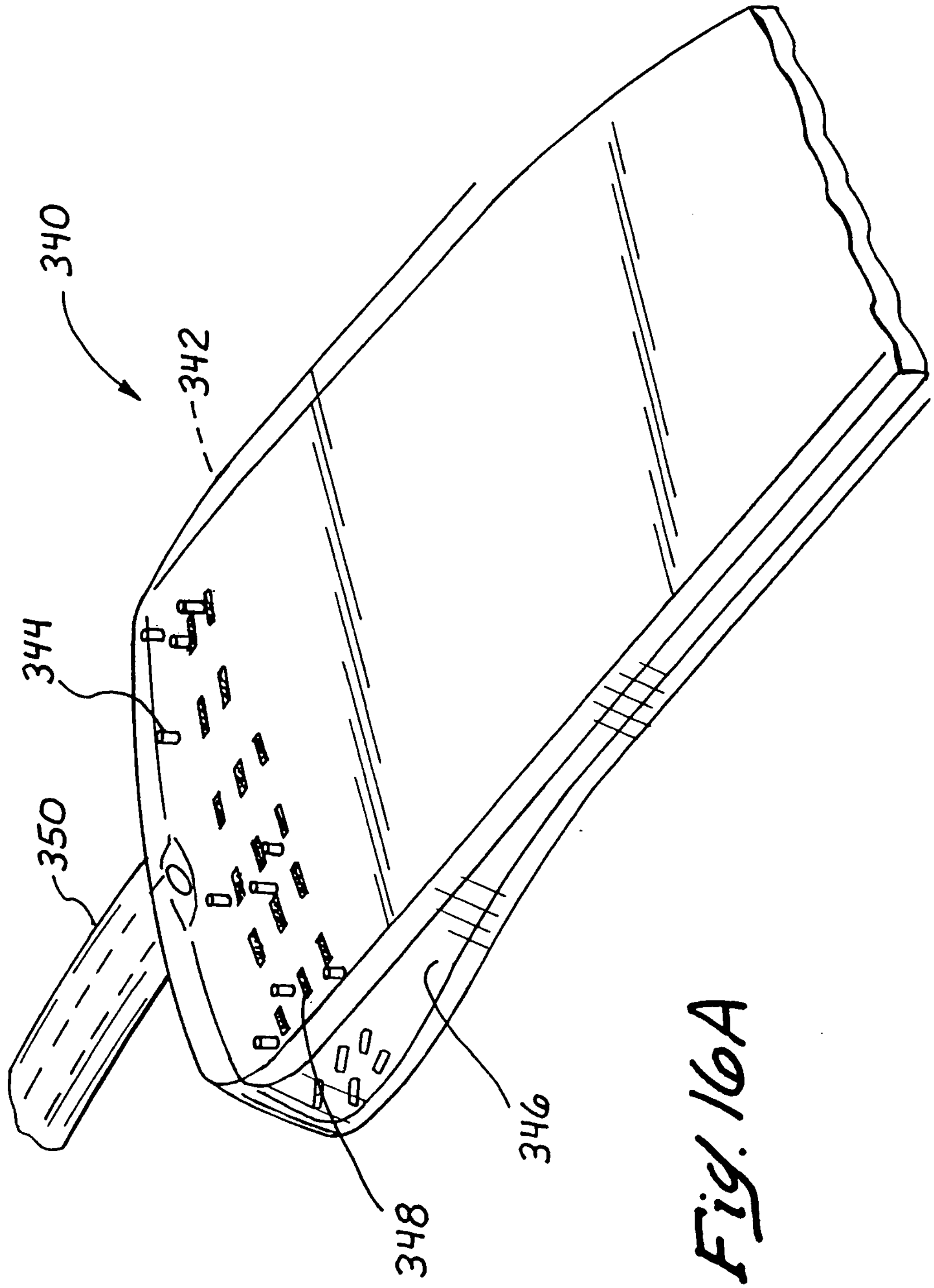


Fig. 16A

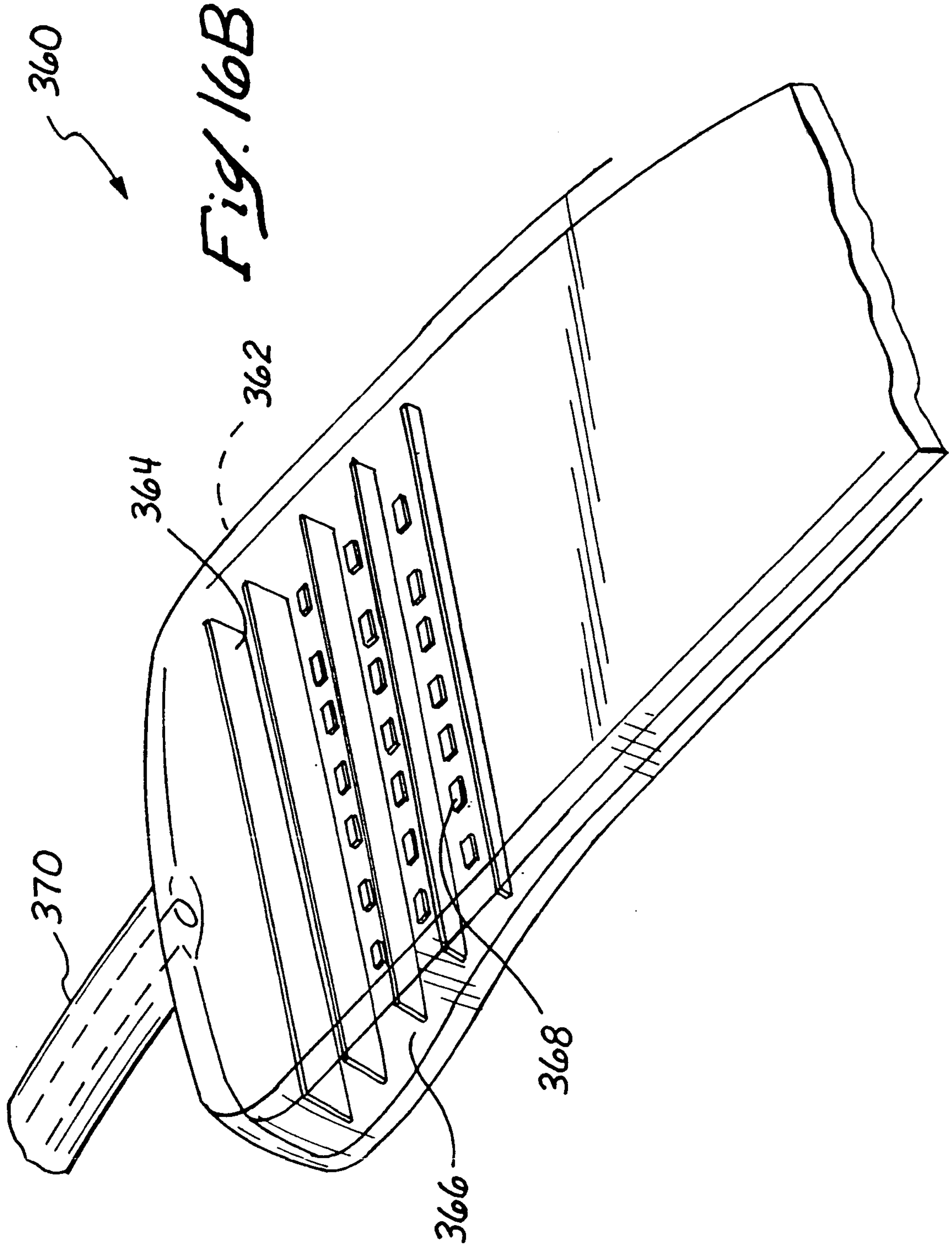


Fig. 16B

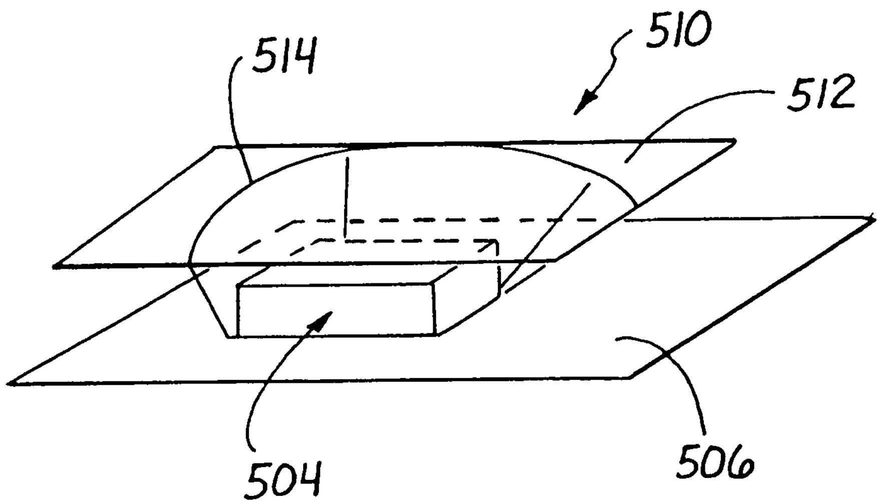


Fig. 17A

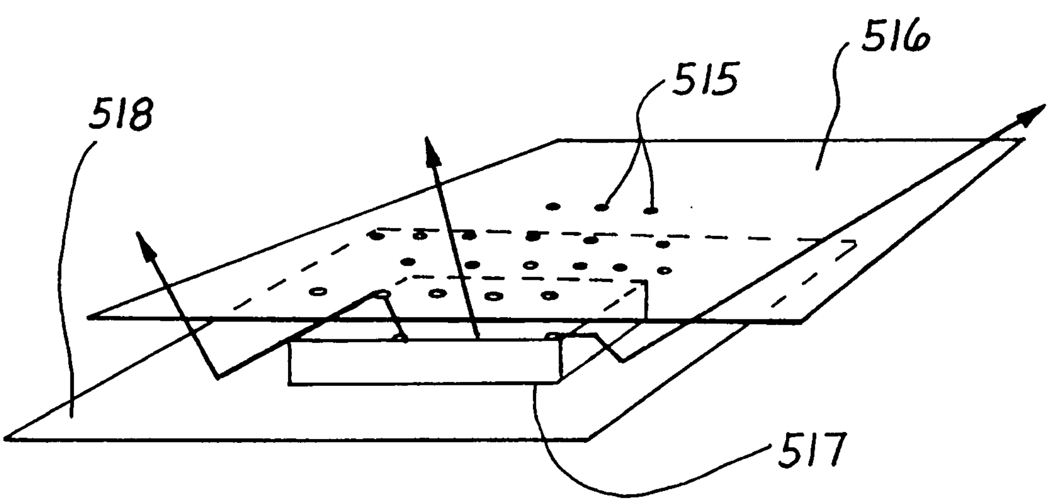


Fig. 17B

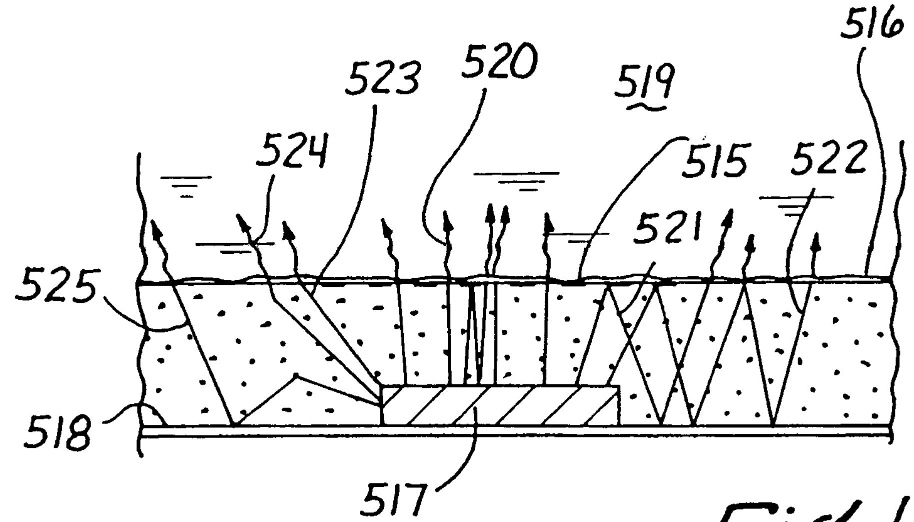


Fig. 17C

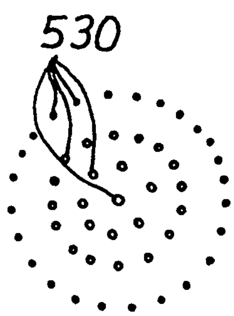


Fig. 18A

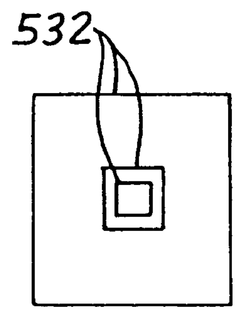


Fig. 18B

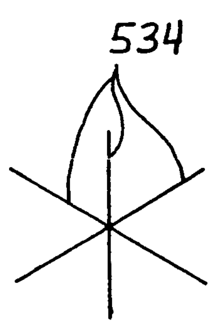


Fig. 18C

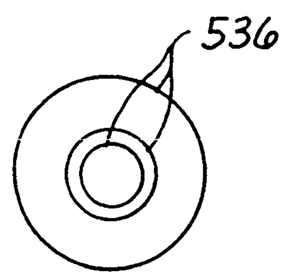


Fig. 18D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/22720

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61N 5/06
US CL : 606/9, 13; 607/88
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/9, 13; 607/88

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,616,140 A (PRESCOTT) 01 April 1997, entire document.	1-8, 11-19, 23-26, 28-34, 37
A	US 5,913,883 A (ALEXANDER et al.) 22 June 1999, entire document.	1-37
A	US 5,634,711 A (KENNEDY et al.) 03 June 1997, entire document.	1-37
A	US 5,800,479 A (THIBERG) 01 September 1998, entire document.	1-37

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03 OCTOBER 2000	26 OCT 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230

Authorized officer
ROY GIBSON
Telephone No. (703) 308-3520